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13. ABSTRACT (Maximum 200) The purpose of this report is to report the results of the first year of a four-year study to investigate and address enlisted Army and Navy women's needs for basic gynecological and reproductive health education in order to enhance military readiness and general well-being. In the first phase of the study, a needs assessment was begun in which the methods included: 1) a mail survey of knowledge, attitudes, and practices (KAP) from a random sample of enlisted Army and Navy women; and 2) focus groups with enlisted Army and Navy women. This first year focused on developing the instruments, beginning approval procedures, conducting the expert panel meeting, and formulating partnerships with co-investigators on Army and Navy installations. Based on the results of the needs assessment, a culturally sensitive, multimedia CD-ROM and accompanying materials will be developed with the help of an advisory panel of military health care providers and with periodic reviews by the target audience. This intervention will then be tested in Army and Navy medical clinics in conjunction with annual Pap test screening.				
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Fort Detrick, Frederick, Maryland 21702-5012

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FOREWORD

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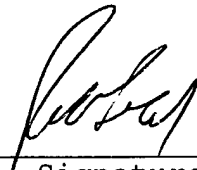
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PI - Signature

10/28/97

Date

Table of Contents

<u>Section</u>	<u>Page</u>
Foreward	3
Table of Contents	4
I. Introduction	5
II. Body: Project Progress	6
Experimental Methods and Procedures	6
Assumptions	8
Results and Discussion	9
Recommendations	11
III. Conclusions	12
Appendix A Enlisted Women's Survey Invitation Letter	
Appendix B Volunteer Agreement Affidavit - Enlisted Women's Survey	
Appendix C Enlisted Women's Survey Questionnaire	
Appendix D Military Clinician Survey Invitation Letter	
Appendix E Military Clinician Survey Questionnaire	
Appendix F Chairperson Survey Invitation Letter	
Appendix G Chairperson Survey Questionnaire	
Appendix H Expert Panel Meeting Report	
Appendix I Single Project Assurance	
Appendix J IRB Project Information Forms, IRB Approval, & Optional Form 310 for each survey	

I. Introduction

The project "CD-ROM Technology to Increase Appropriate Self-Care and Preventive Behaviors Among Army and Navy Women" was initiated as a way to study and address the reproductive health education needs of enlisted Army and Navy women. Not only is the ability of each female soldier to protect and control her reproductive health essential to military readiness, it is important for these women's quality of life.

The purpose of the study is to investigate enlisted women's needs for basic gynecological and reproductive health education, from the perspective of military health care providers and enlisted women themselves. Based on the results of the needs assessment, a culturally sensitive, multimedia CD-ROM and accompanying materials will be developed. This intervention will then be tested in Army and Navy medical clinics in conjunction with annual Pap test screening.

This report describes the first year of operation of the project, which began in September 1996. The project is a four year study with three distinct phases: a needs assessment phase, a design phase, and an efficacy study phase. The first year was to include the needs assessment phase and the beginning of the application design. Due to delays in questionnaire design and human subjects approval, the needs assessment phase is still in operation.

The previous work for this project included a literature review, review of Institute of Medicine recommendations for Defense Women's Health, and discussions with military and medical personnel. This work was the basis of the proposal submitted to the U.S. Army Medical Research and Materiel Command. Since the initiation of the project, we have conducted an expert panel meeting, developed and pilot tested survey instruments for the needs assessment, and completed IRB review by Macro International. We have also drafted focus group interview guides and begun survey approval through Department of Defense Health Affairs and the Defense Manpower Data Center. We have begun to develop partnerships with co-investigators from two Army bases and two Navy bases for conduct of the needs assessment surveys. This report will summarize these activities and our future task timeline.

II. Body: Project Progress

The experimental methods and procedures reported here represent an amalgamation of methods originally proposed and those which resulted from recommendations of representative from our expert panel and human use committees.

A. Experimental Methods and Procedures

The purpose of the study is to investigate enlisted women's needs for basic gynecological and reproductive health education, as evidenced by a needs assessment process to be conducted with military health care providers and enlisted women themselves. Based on the results of the needs assessment, a culturally sensitive, multimedia CD-ROM and accompanying materials will be tested in an Army and Navy medical clinic in conjunction with annual Pap test screening. The technical objectives are as follows:

- 1) To assess the most pressing reproductive and gynecological self-care education needs of enlisted women on base and in the field;
- 2) To assess the range of current health education efforts for enlisted women;
- 3) To enhance enlisted women's self-care and care-seeking knowledge and practices through development and implementation of a culturally sensitive, multimedia educational intervention and accompanying field pocket guide at a medical clinic.

The study involves 4 data gathering activities that involve human subjects:

- 1) Needs assessment mail surveys conducted with nationally representative samples of enlisted women in the Army and Navy (N=500), military health care providers (n=260), and chairpersons of military base OB/GYN services (N=160);
- 2) Needs assessment focus groups with enlisted women in the Army and Navy (N=40) and military health care providers (N=20);
- 3) Alpha Test of prototype intervention with 10 enlisted women at the Uniformed Services University of the Health Sciences (USUHS); and
- 4) Efficacy Study in which 528 enlisted women (264 from the Army and 264 from the Navy) complete a knowledge, attitudes, and practices (KAP survey) before the intervention, immediately after the intervention, at 6 month follow up, and at 12 month follow up.

1. Human Subject Involvement and Characteristics

1) Enlisted Women's Survey

All of the enlisted women will be volunteers for the study. They will be recruited via mail surveys sent to a nationally representative sample of each group. A two-stage cluster sample will be used

to sample enlisted women who will be sent the needs assessment survey. A sample of 4 clusters (military bases), with a subsample of 125 individuals taken in each cluster, will be drawn.

Five hundred enlisted women in the Navy and the Army residing at military bases in the United States will be mailed a survey with an invitation to participate (Appendix A has the invitation letter, postcard text, and slip sheet text) as well as a Volunteer Agreement Affidavit (Appendix B), and postage-paid return envelope. If no response is received, a second survey will be mailed. If there is still no response, a third survey will be sent via certified mail. The survey instrument is in Appendix C.

2) Military Clinician's Survey

The respondents will be volunteers for the study. They will be recruited via mail surveys sent to a nationally representative sample of each group.

A total of 260 military health care providers providing OB/GYN services to enlisted women at U.S. military bases. The sample will be based upon approximately 1,000 OB/GYN providers across the 250 military bases in the U.S., for a sub-sample of 4 providers per base at 65 bases (N=260). The clinicians will be mailed a survey with an invitation letter (Appendix D) and a postage-paid return envelope. If no response is received, a second survey will be mailed. If there is still no response, a third survey will be sent via certified mail. The clinician survey is in Appendix E.

3) Chairperson Survey

The survey respondents be volunteers for the study. They will be recruited via mail surveys sent to a representative sample of each group.

A total of 160 Chairpersons of U.S. military medical departments serving enlisted women. A representative sample of 160 military bases will be drawn from 250 military bases around the country. The 4-page survey will be mailed directly to the chairperson of OB/GYN, the troop medical clinic (TMC) or "Sick Call" clinic, or family practice at the medical center of each base, depending upon which department is primarily responsible for the reproductive health care of enlisted women. These individuals will mailed a survey with an invitation letter (Appendix F) and postage-paid return envelope. If no response is received, a second survey will be mailed. If there is still no response, a third survey will be sent via certified mail. The chairperson survey is in Appendix G.

2. Human Subject Procedures

1) Enlisted Women's Survey

Enlisted women will be sent a knowledge, attitudes, and practices (KAP) survey for enlisted women regarding current knowledge levels, self-care and preventive behaviors and attitudes, and use of and

attitudes toward medical care services (see Appendix C). The surveys will be mailed to each participant with an invitation letter (consent form) and postage-paid return envelope. If no response is received, a second survey will be mailed. If there is still no response, a third survey will be sent via certified mail. Respondents who choose to return a self-addressed postcard to the investigators will be eligible for an incentive. One woman per base will be able to win a \$100 gift certificate at the base's PX.

2) Clinician Survey

Military health care providers will be asked to fill out the survey question (on knowledge, attitudes, and practices regarding the reproductive health) and mail the completed questionnaire to the investigators in a envelope with prepaid postage. See Appendix E for the questionnaire.

3) Chairperson Survey

Military base chairpersons will be asked to complete a survey about current medical care practices and health education efforts specifically targeted to enlisted women. The survey will be mailed directly to the chairperson of departments serving the reproductive needs of enlisted women (OB/GYN, family practice, Troop Medical Clinic, Sick Call) at the medical services at each base. Two follow-up surveys will be sent to non-respondents, the second by certified mail. All surveys will have postage-paid return envelopes included in the package. See Appendix G for the questionnaire.

B. Assumptions

The principal assumptions for the current project fall into several areas: operational and substantive.

Operational Assumptions

1. The broadest possible benefit to enlisted women would come from broad representation from two services, the Army and the Navy.
2. Among those two services, our primary target audience for training is the enlisted women. Our secondary target audience for training is military clinicians providing reproductive health care to enlisted women.

Substantive Assumptions

1. Following human subject and other clearances, the project would begin with a needs assessment that included attention to service women and health services personnel, both clinicians and their administrators.

2. A multimedia CD-ROM could be used to address the health education needs of military women, and use of a CD-ROM would be possible in military settings.

These broad assumptions guided the development of the strategies outlined in the original survey and clarified during the first year of project operation.

C. Results and Discussion

This section is a detailing of year one activities and results. It is not yet a final project report with a full listing project outcomes. Table 1 lists the major activities of the first project year in terms of the two tasks outlined in the original proposal.

Table 1: Major Activities of the First Project Year		
Task	Description	Months of Performance
1	Convene advisory panel	1-3
2	Develop needs assessment surveys	2-4
2	Pilot test needs assessment surveys	4-9
2	IRB review of surveys and survey protocol	10
2	Preliminary review by the Human Use and Regulatory Affairs	11
2	DoD Health Affairs review of needs assessment surveys	12
2	Develop partnerships with co-investigators at Army and Navy bases.	1, 9-12

1. Expert Panel

The first expert panel meeting was held on December 2 and 3, 1996. A full report of the meeting is contained in Appendix H. Highlights include the development of a vision statement, health outcomes, and behavioral objectives.

2. Instrument Development

In keeping with expert panel review and feedback in the development of the needs assessment

surveys, an iterative process was used. Refer to Figure 1 for the task and timeline for instrument development.

Figure 1: Timeline for Instrument Development

November 1996:	First draft of surveys
December 1996:	Presented surveys to expert panel, gathered and incorporated their input
January 1997:	Involved Army health promotion expert in the expert panel, gained her input. Gathered input from other experts.
February 1997:	Final review of expert panel
March 1997:	Prepared for pilot test
April 1997:	Sent out enlisted women surveys and clinician surveys to USUHS to distribute to volunteers
May 1997:	Sent out surveys to chairs of military medical clinics and departments, including: OB/GYN, Sick Call, Troop Medical Clinic, Military and Emergency Medicine, Family Medicine

The instruments are located in Appendix C (enlisted women's survey), Appendix E (clinician survey), and Appendix G (chairperson survey).

3. Human Subjects Approval

Prior to the beginning of the project, Macro International completed a Single Project Assurance (SPA) application with the U. S. Army Medical Research and Materiel Command (USAMRMC). The SPA is in Appendix I. In accordance with the SPA, project management has maintained close contact with Macro's IRB. Pursuant to a directive issued by the IRB, an initial review meeting took place upon completion of the instruments, in July 1997. The project information forms, approval letters from IRB, and Optional Form 310 are in Appendix J. The clinician and chairperson surveys were recommended for exemption.

We worked together with the Human Use Review and Regulatory Affairs Division. The survey instruments and related documentation were forwarded to them following Macro's IRB review. This strategy was based upon guidance given on August 4, 1997, at a meeting at Ft. Detrick. Subsequent to this meeting, we were directed to submit the surveys to Department of Defense (DoD) Health Affairs in order to obtain a "Report Control Symbol." The surveys are currently being reviewed. Once a report control symbol is obtained, the survey instruments and related information will be forwarded to the Human Use Review and Regulatory Affairs Division.

4. Developing Partnerships

The enlisted women's survey will be conducted at two Army and two Navy bases. Based on recommendations from expert panel members, the Navy Clinical Investigations Department, and the Army Clinical Investigations Department, we were recommended to establish working partnerships with investigators at each base. These investigators will facilitate gaining access to troop populations and will assist in clearance procedures. We have verbal agreements with investigators from 4 military bases (Table 2).

Table 2: Targeted Installations for Needs Assessment Partnership		
Region	Army	Navy
East Coast	Ft. Bragg North Carolina	Portsmouth Naval Base Virginia
West Coast	Ft. Lewis Washington	Naval Station San Diego California

D. Recommendations

Our experiences in the first year of the project have clarified how to proceed with our statement of work. Two clear recommendations emerge.

First, we should maintain between investigators and the Human Use Review and Regulatory Affairs Division. The complexity of the clearance process in multi-service research necessitates vigilance as well as a clear understanding of how the clearance process works. In the absence of broad service clearance procedures, attention to differences in the procedures becomes more critical.

Second, based on expert panel recommendations, we need to involve other clinicians and services that provide reproductive health care to enlisted women. Originally we proposed to examine OB/GYN physicians and services. However, family medicine, emergency services, and troop medical clinics also provide routine and acute gynecologic care to these soldiers. Also, nurse

practitioners, physician assistance, and other allied health professionals often provide direct patient care. Therefore, we have modified our needs assessment to include these services and clinicians.

III. Conclusions

Because the project is only a year old and not even the needs assessment is complete, we cannot yet draw conclusions. In lieu of conclusions, however, we will list barriers we have faced and how we addressed those. We will also list the activities anticipated for the next year of operation.

1. Absence of single office clearance for multi-service research projects

In any setting, whenever more than one voice provides guidance, there is the potential for inconsistent, conflicting, and incomplete information. In our first year, we faced all three of these challenges. Meeting with representatives of the Command and the Human Use Review and Regulatory Affairs Division was opportune and suggests for us a strategy should similar problems occur in the future.

2. Overly ambitious proposed project plan

Our inexperience with military research allowed us to propose a schedule that was not likely to be satisfied. Even if the surveys had been developed and approved on schedule, data collection and analysis was unlikely to be completed within the first six months of the project as proposed. We will work with the Command to establish more reasonable milestones as the project progresses.

Over the next year of the project, we plan to conduct the following activities:

- conduct the needs assessment surveys;
- conduct the needs assessment focus groups;
- compile the findings of the data collection;
- produce a design document and plan for the multimedia application;
- settle on final design specifications for the multimedia application, recognizing recent advances in communications technology; and
- establish preliminary agreements with bases who will participate in the field test of the application.

Appendix A

Invitation Letter for Enlisted Women's Needs Assessment Survey

Date

Address

Re: Participation in a study "CD-ROM Technology to Increase Appropriate Self-Care and Preventive Behaviors Among Army and Navy Women"

Civilian Principal Investigator: Dr. Robert S. Gold, Ph.D., Dr.P.H.

Military Principal Investigator: Dr. Evelyn Lewis, M.D.

Dear _____:

We need your help in an important survey of the most pressing self-care and preventive education needs of enlisted women concerning their reproductive health. This study is funded by the U.S. Army Medical Research and Materiel Command (USAMRMC). Macro International Inc., a private research/consulting firm, is conducting the research study with the Uniformed Services University of the Health Sciences (USUHS). This study is important because the number of women in the U.S. Armed Forces is increasing, and the Department of Defense is concerned about their health needs. The results of the survey will be used to help develop educational materials on reproductive health for enlisted women.

You are one of approximately 500 enlisted women in the Army and Navy who have been randomly selected from several bases across the country to participate by completing this needs assessment survey. Independently, we also plan to survey a random sample of military health care providers and the chairpersons of military medical departments which provide reproductive health care to enlisted women. Apart from the national significance of this survey, we are providing you with an additional incentive to return your completed questionnaire. **One participating enlisted woman from your base will win a \$100 gift certificate to her base's PX.** To be eligible to win, return the enclosed (color) postcard with your name and address. The drawing for the prize will be held (date) .

Your responses will be safeguarded to the fullest extent possible in accordance with applicable statutes. The identification number on the questionnaire allows us to send a reminder to enlisted women who do not return surveys. The names and addresses corresponding to the identification numbers will be kept in a locked file available only to authorized Macro staff. Upon receiving your survey, we will destroy all information that would allow linking your answers with you. Neither U.S. Army nor U.S. Navy staff will be given the information needed to link individual responses with identifying information of any type.

Please read the attached Volunteer Agreement Affidavit. To participate in the survey, fill out both copies the attached Volunteer Agreement Affidavit. Keep this letter and a copy of the Volunteer Agreement Affidavit and return the other copy with your filled out survey to the civilian principal investigator, Dr. Robert Gold, in the enclosed prepaid envelope. If you have misplaced the envelope enclosed with the survey, send your completed survey to: DOD Women's Health Survey, Macro International Inc., 126 College Street, Suite 2A, Burlington, VT 05401-9951.

If you have any questions or need any more information, please call Nancy Meyer at Macro International Inc. at 1-800-###-####. We thank you for your time, and look forward to your participation in this important study.

Robert Gold, Ph.D., Dr. P.H.
Civilian Principal Investigator

Dr. Evelyn Lewis, CDR. MC, USN-USUHS
Military Principal Investigator

(Color) Postcard

DOD Women's Health Survey
Macro International Inc.
11785 Beltsville Drive
Calverton, MD 20705

**THANK YOU FOR YOUR PARTICIPATION
IN THIS IMPORTANT SURVEY!**

To enroll in our drawing for a \$100 gift certificate for the PX on your base, or to receive a copy of the survey results, fill out this postcard with your name and address.

☐ I would like to enroll in the drawing for a
\$100 gift certificate

☐ I would like to receive a report of the
survey results.

(Initial Slipsheet)

ENTER NOW! YOU COULD BE A WINNER!

Enter now and your completed suvey will automatically enroll you in our drawing
for a \$100 gift certificate for the PX on your base!

The drawing will be held (date) .

One prize will be awarded to each participating base.

(Follow-up Slipsheet)

HAVE YOU ALREADY COMPLETED THIS SURVEY?

It is possible that your responses have crossed in the mail with this notice.

If so, please disregard this packet.

If not...

ENTER NOW! YOU COULD BE A WINNER!

Enter now and your completed suvey will automatically enroll you in our drawing
for a \$100 gift certificate for the PX on your base!

The drawing will be held (date) .

Appendix B

**Volunteer Agreement Affidavit
for Enlisted Women's
Needs Assessment Survey**

VOLUNTEER AGREEMENT AFFIDAVIT

For use of this form, see AR 70-25 or AR 40-38; the proponent agency is OTSG

PRIVACY ACT OF 1974

Authority: 10 USC 3013, 44 USC 3101, and 10 USC 1071-1087.

Principal Purpose: To document voluntary participation in the Clinical investigation and Research Program. SSN and home address will be used for identification and locating purposes.

Routine Uses: The SSN and home address will be used for identification and locating purposes. Information derived from the study will be used to document the study. Implementation of medical programs; adjudication of claims; and for the mandatory reporting of medical conditions as required by law. Information may be furnished to Federal, State and local agencies.

Disclosure: The furnishing of your SSN and home address is mandatory and necessary to provide identification and to contact you if future information indicates that your health may be adversely affected. Failure to provide the information may preclude your voluntary participation in the investigational study.

PART A(1) - VOLUNTEER AFFIDAVIT

Volunteer Subjects in Approved Department of the Army Research Studies

Volunteers under the provisions of AR 40-38 and AR 70-25 are authorized to give all necessary medical care for injury or disease which is the proximate result of their participation in such studies.

I, _____, SSN N/A,
having full capacity to consent and having attained my eighteenth birthday, do hereby volunteer/give consent as legal
representative for myself to participate in CD-ROM Technology To Increase Appropriate
Self-Care and Preventive Behaviors Among Army and Navy Women
(Research study)

under the direction of Dr. Robert S. Gold, Civilian P.I.; Dr. Evelyn Lewis, Military P.I.

conducted at Macro International Inc., Uniformed Services University of the Health Sciences

(Name of institution)

The implications of my voluntary participation/consent as legal representative; duration and purpose of the research study; the methods and means by which it is to be conducted; and the inconveniences and hazards that may reasonably be expected have been explained to me by

Dr. Robert S. Gold, Civilian Principal Investigator

I have been given an opportunity to ask questions concerning this investigational study. Any such questions were answered to my full and complete satisfaction. Should any further questions arise concerning my rights/the rights of the person I represent on study-related injury, I may contact

James G. Ross, Vice President, IRB Chairperson

at Macro International Inc., 11785 Beltsville Drive, Calverton, MD 20705 (301) 572-0200

(Name, Address and Phone Number of Hospital (Include Area Code))

I understand that I may at any time during the course of this study revoke my consent and withdraw/have the person I represent withdrawn from the study without further penalty or loss of benefits; however, I/the person I represent may be required (military volunteer) or requested (civilian volunteer) to undergo certain examination if, in the opinion of the attending physician, such examinations are necessary for my/the person I represent's health and well-being. My/the person I represent's refusal to participate will involve no penalty or loss of benefits to which I am/the person I represent is otherwise entitled.

PART A(2) - ASSENT VOLUNTEER AFFIDAVIT (MINOR CHILD)

I, N/A, SSN N/A, having full
capacity to assent and having attained my N/A birthday, do hereby volunteer for _____
to participate in _____
N/A
(Research Study)

under the direction of N/A

conducted at N/A

(Name of institution)

(Continue on Reverse)

PART A(2) - ASSENT VOLUNTEER AFFIDAVIT (MINOR CHILD) (Cont'd.)

The implications of my voluntary participation; the nature, duration and purpose of the research study; the methods and means by which it is to be conducted; and the inconvenience and hazards that may reasonably be expected have been explained to me by

N/A

I have been given an opportunity to ask questions concerning this investigational study. Any such questions were answered to my full and complete satisfaction. Should any further questions arise concerning my rights I may contact

N/A

at N/A

(Name, Address, and Phone Number of Hospital (Include Area Code))

I understand that I may at any time during the course of this study revoke my assent and withdraw from the study without further penalty or loss of benefits, however, I may be requested to undergo certain examination if, in the opinion of the attending physician, such examinations are necessary for my health and well-being. My refusal to participate will involve no penalty or loss of benefits to which I am otherwise entitled.

N/A

PART B - TO BE COMPLETED BY INVESTIGATOR

INSTRUCTIONS FOR ELEMENTS OF INFORMED CONSENT: *(Provide a detailed explanation in accordance with Appendix C, AR 40-38 or AR 70-25.)*

Description of Study: This study is a 4-year research project to investigate enlisted women's needs for basic gynecological and reproductive health education and to develop a culturally sensitive, multimedia CD-ROM and accompanying educational materials based on those needs. The CD-ROM and educational materials will be tested with enlisted women attending Army and Navy medical clinics during annual Pap test appointments. This study is important because the number of women in the U.S. Armed Forces is increasing, and statistics show that the rate of unintended pregnancies, sexually transmitted diseases (STDs), and common preventable gynecological conditions, such as vaginitis, warrant immediate attention by both enlisted women and health care providers.

This is the first phase of the study, the needs assessment. Subject participation is limited to the completion of this survey. The survey asks enlisted women about their knowledge of basic female physiology (body functions), what they need to know and want to know about their health, their experiences with military medical care, and their knowledge of current health education efforts for enlisted women. Finally, the survey asks enlisted women their opinions about using a CD-ROM program to obtain education on health and self-care important to military women. The survey should take about a half hour to an hour to complete.

Risks: There are no foreseeable risks to participating in this study.

Benefits: Enlisted women participating in the needs assessment survey may have an increased awareness about their health and health care needs. They may also experience indirect benefits from improved women's health programming should the study facilitate the development of an effective intervention.

Confidentiality: Neither names nor any other personal information will be placed on the survey form. Instead, a unique identification number will be used to link surveys to personal information. Only the Principal Investigators will have access to the information that links surveys with personal information, which will be destroyed when we receive your completed survey. All data and medical information obtained will be considered privileged and held in confidence; enlisted women who volunteer to participate will not be identified in any presentation of the results. Complete confidentiality cannot be promised, particularly to subjects who are military personnel, because information bearing on your health may be required to be reported to appropriate medical or command authorities. It should be noted that representative of the U.S. Army Medical Research and Materiel Command are eligible to review research records as a part of their responsibility to protect human subjects.

Compensation: There is no other compensation available for participation in this research study; however, this is not a waiver or release of your legal rights.

Questions about the Study: Questions about the study should be directed to Nancy Atkinson Meyer, Project Director, Macro International Inc., 11785 Beltsville Drive, Calverton, MD, 20705. Telephone: (301)572-0200.

I do ☐ do not ☐ *(check one & initial)* consent to the inclusion of this form in my outpatient medical treatment record.

SIGNATURE OF VOLUNTEER	DATE	SIGNATURE OF LEGAL GUARDIAN (IF VOLUNTEER IS A MINOR) N/A	
PERMANENT ADDRESS OF VOLUNTEER	TYPED NAME OF WITNESS N/A		
	SIGNATURE OF WITNESS N/A		DATE

Appendix C

**Enlisted Women's Survey
Questionnaire**

Health Needs of Enlisted Army and Navy Women

The purpose of this survey is to collect information about health knowledge, attitudes, and behavior of enlisted Army and Navy women. The information you provide will help to identify and design the health programs and services enlisted women in the Army and Navy need.

The survey asks several questions about sensitive issues such as sexual behavior and feminine hygiene/cleanliness practices. We realize it makes some people uncomfortable to answer questions about sexual practices. Some people feel that they should answer a certain way, even if they are doing something else. To get good information, it is important to know what enlisted Army and Navy women know, think, and do.

Completing the survey is voluntary. You will not be penalized for not responding to any particular question. However, your participation is encouraged so that the data will be complete and representative.

Some people feel uncomfortable answering sensitive questions on a survey because it is written. The answers you give will be safeguarded to the fullest extent possible in accordance with the applicable statutes. Once we receive your survey, we will destroy the information linking your answers with any personal information, so your answers will then be anonymous. Also, your answers will be combined with the answers of hundreds of other enlisted women in the Army and Navy who complete this survey. No individual enlisted women will be identified when we present the results of the survey, so please answer every question as honestly as you can.

Do not write your name on this survey.

When you are finished, send back the completed survey in the return envelope with your signed consent form. No postage is necessary.

Thank you very much for your help.

Health Needs of Enlisted Army and Navy Women

I. Demographics—Mark only one answer to each question unless you are asked to check all that apply.

1. What is your sex?

- ☐ Female
- ☐ Male

If you are "Male," do not answer any other questions. This survey is for enlisted women.

2. How old are you? _____ Years

3. In what branch of the Armed services do you serve?

- ☐ Army
- ☐ Navy
- ☐ Other (Specify): _____

4. What is your grade? (Check one.)

- ☐ E1-E2
- ☐ E3-E4
- ☐ E5-E6
- ☐ E7-E9
- ☐ I am an officer.

5. When did you enter the service?

Month _____ Year _____

6. How long do you plan to be in the service? (Count from your date of entry.)

_____ Years

7. What is your primary job in the military?

- ☐ Health Care
- ☐ Administrative
- ☐ Communications/Intelligence
- ☐ Engineering/Maintenance
- ☐ Supply and Service
- ☐ Scientific/Professional
- ☐ Combat
- ☐ Other (Specify): _____

8. What type of deployment experience do you have? (Check all that apply.)

- ☐ None
- ☐ Field exercises
- ☐ Combat duty
- ☐ Humanitarian missions
- ☐ Other (Specify): _____

9. How do you describe yourself?

- ☐ White—not Hispanic
- ☐ Black—not Hispanic
- ☐ Hispanic or Latino
- ☐ Asian or Pacific Islander
- ☐ American Indian or Alaskan Native
- ☐ Other (specify): _____

10. What is your marital status?

- ☐ Single, never married
- ☐ Living with someone of the opposite sex with whom you have a relationship
- ☐ Married, living with your husband
- ☐ Married, not living with your husband
- ☐ Legally separated
- ☐ Divorced
- ☐ Widowed

11. Where do you currently live?

- ☐ Barracks
- ☐ Other base housing
- ☐ Off-base housing
- ☐ Other (Specify): _____

12. With whom do you currently live? (Check all that apply.)

- ☐ Alone
- ☐ Spouse/domestic partner
- ☐ Roommate(s)/friend(s)
- ☐ Parent(s)/guardian(s)
- ☐ Other relatives
- ☐ Your children
- ☐ Other

Health Needs of Enlisted Army and Navy Women

13. What is the highest education level you have completed and received credit for?

- ☐ High school diploma
- ☐ GED
- ☐ Associate's degree
- ☐ Vocational degree
- ☐ Some college
- ☐ Bachelor's degree
- ☐ Graduate degree

14. What is your religious preference?

- ☐ Protestant
- ☐ Jewish
- ☐ Catholic
- ☐ Other
- ☐ No preference

15. Did you grow up in a military family?

- ☐ Yes
- ☐ No

16. Where did you spend most of your childhood years? (Where did you grow up?)

- ☐ In the country (rural area)
- ☐ In a large city (urban area)
- ☐ In an inner city neighborhood
- ☐ In a town
- ☐ In a suburb
- ☐ Several places (non military family)
- ☐ Overseas

II. Knowledge—Read each of the following questions, and select the answers you think are correct. It is important that we find out what women do and do not know, so please do not discuss your answers with anyone or ask anyone for help in answering the questions. You are **not** expected to know all the correct answers. Mark only one answer.

17. When does the ovulation phase of the female reproductive cycle usually occur?

- ☐ Right before a woman's period
- ☐ During a woman's period
- ☐ Right after a woman's period
- ☐ Mid-cycle
- ☐ I don't know.

18. What is the best method for cleaning the vagina?

- ☐ Using a vinegar and water douche
- ☐ Using vaginal deodorants
- ☐ Letting normal secretions cleanse the vagina
- ☐ Using Deodorant soap
- ☐ I don't know

19. Which is the best way to clean the vagina in the field?

- ☐ With scented deodorant sprays
- ☐ With disposable wipes
- ☐ By drinking plenty of water
- ☐ There is no way to be clean in the field.
- ☐ I don't know.

20. How can a woman be sure she has **NO** sexually transmitted diseases (STDs)?

- ☐ When she has no symptoms of itching or burning
- ☐ When she has a normal Pap test
- ☐ When her doctor does not notice any problems
- ☐ When screening tests show no infection
- ☐ I don't know.

21. What is the most common reason that birth control methods fail among American women?

- ☐ Incorrect use
- ☐ Method does not work well
- ☐ Lack of directions
- ☐ Poor choice of method
- ☐ I don't know

Health Needs of Enlisted Army and Navy Women

22. Which of the following is an effective method of birth control?
- ☐ Condoms
 - ☐ Withdrawal
 - ☐ Calendar method (rhythm)
 - ☐ Douching
 - ☐ I don't know.
23. At what point in the monthly reproductive cycle can a woman most likely become pregnant?
- ☐ Just after period (menstrual phase)
 - ☐ Just before period (menstrual phase)
 - ☐ Within one day of ovulation
 - ☐ Four days after ovulation
 - ☐ I don't know

For the following questions, check whether the statements that finish the phrase are true or false. If you do not know the answer, circle "Don't know."

24. What should enlisted women do to prepare for deployment?
- | | | | |
|---|------|-------|------------|
| a. Have an OB/GYN exam | True | False | Don't Know |
| b. Have a pregnancy test | True | False | Don't Know |
| c. Stop using birth control | True | False | Don't Know |
| d. Pack plenty of personal hygiene supplies | True | False | Don't Know |
25. Being assertive in sexual matters means:
- | | | | |
|---|------|-------|------------|
| a. Taking responsibility for protection against disease and pregnancy | True | False | Don't Know |
| b. Relying on your partner to be responsible for protection against disease and pregnancy | True | False | Don't Know |
| c. Saying no to a partner when necessary | True | False | Don't Know |
| d. Talking with a partner about sex | True | False | Don't Know |
26. Sexually transmitted diseases (STDs) can lead to all the following health problems:
- | | | | |
|--------------------------------------|------|-------|------------|
| a. Premenstrual syndrome (PMS) | True | False | Don't Know |
| b. Cervical cancer | True | False | Don't Know |
| c. Infertility/sterility | True | False | Don't Know |
| d. Pelvic inflammatory disease (PID) | True | False | Don't Know |
| e. Endometriosis | True | False | Don't Know |
27. The risk of an STD infection is increased by:
- | | | | |
|--|------|-------|------------|
| a. Having many steady boyfriends with whom one has had sex | True | False | Don't Know |
| b. Having sex when drunk or high | True | False | Don't Know |
| c. Having sex when dirty | True | False | Don't Know |
| d. Having sex without a barrier method, such as condoms | True | False | Don't Know |

28. A woman can minimize sexual health problems in the field by:

- | | | | | |
|----|--|------|-------|------------|
| a. | Using condoms if any sexual contact occurs | True | False | Don't Know |
| b. | Cleaning genitals with scented products | True | False | Don't Know |
| c. | Wearing cotton underwear | True | False | Don't Know |
| d. | Cleaning genitals with water | True | False | Don't Know |

29. Enlisted women who become pregnant are more likely to experience:

- | | | | | |
|----|--|------|-------|------------|
| a. | Mandatory discharge from the military | True | False | Don't Know |
| b. | Fewer career/advancement opportunities | True | False | Don't Know |
| c. | Avoidance of field duty | True | False | Don't Know |
| d. | Avoidance of physical training (PT) | True | False | Don't Know |
| e. | Reassignment to non-deployable status | True | False | Don't Know |
| f. | Harassment from peers/commander | True | False | Don't Know |
| g. | Light duty assignment | True | False | Don't Know |

30. Yeast infections are **more common** among women who:

- | | | | | |
|----|--------------------------|------|-------|------------|
| a. | Are pregnant | True | False | Don't Know |
| b. | Have diabetes | True | False | Don't Know |
| c. | Take birth control pills | True | False | Don't Know |
| d. | Do not douche | True | False | Don't Know |

A. Attitudes Toward Sexually Transmitted Disease (STD) Infection and Condoms

31. What is the chance that you will get an STD within the next 12 months? (Circle one)

[illegible]

32. What is the chance that the typical enlisted Army/Navy woman will get an STD within the next 12 months? (Circle one)

[illegible]

Health Needs of Enlisted Army and Navy Women

46. My friends think it is important to use condoms to prevent STDs.

Strongly
Agree

Agree

Unsure

Disagree

Strongly
Disagree

If you have never had sexual intercourse, go to question number 57.

47. In general, what is your current (or most recent) sexual partner's attitude toward using condoms?

Very
Positive

Positive

Neutral

Negative

Very
Negative

Put an X in the box that most closely describes how your current (or most recent) sexual partner feels about condoms.

48. Embarrassing to discuss

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------

Easy to discuss

49. Improve love making

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------

Spoil love making

50. Easy to use

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------

Hard to use

51. Reduce sexual pleasure

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------

Enhance sexual pleasure

52. Easy to use every time

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------

Hard to use every time

53. Builds trust

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------

Destroys trust

54. I am confident that my partner(s) and I can use condoms correctly to prevent STDs.

Strongly
Agree

Agree

Unsure

Disagree

Strongly
Disagree

55. I am confident that my partner(s) and I can use condoms to prevent STDs every time we have intercourse.

Strongly
Agree

Agree

Unsure

Disagree

Strongly
Disagree

56. I am confident that my partner and I can use condoms to prevent STDs if we have been drinking alcohol or using drugs.

Strongly Agree

Agree

Unsure

Disagree

Strongly Disagree

Earlier we asked you a series of questions about how you feel about STDs and condoms. Now we would like to know how you feel about **unintentional pregnancy and contraception** (birth control) in general.

57. What is the chance that you will have an unplanned pregnancy within the next 12 months?

[illegible]

58. What is the chance that the typical enlisted Army/Navy woman will have an unplanned pregnancy within the next 12 months?

[illegible]

59. What is the chance that the typical civilian woman will have an unplanned pregnancy within the next 12 months?

[illegible]

60. When you have sexual intercourse, what birth control method do you **usually** use to prevent pregnancy? **(Check all that apply.)**

- ☐ No method
- ☐ Withdrawal
- ☐ Birth control pills
- ☐ Norplant
- ☐ Depo-Provera
- ☐ Diaphragm
- ☐ Male condom (latex or polyurethane)
- ☐ Male condom (natural)
- ☐ Female condom
- ☐ Spermicide (foam, film, etc.)
- ☐ Tubal ligation
- ☐ Vasectomy
- ☐ Other: _____
- ☐ I've never had sexual intercourse

61. In general, what is your attitude toward using birth control (contraception)?

Very
Positive

Positive

Neutral

Negative

Very
Negative

Health Needs of Enlisted Army and Navy Women

Put an X in the box that most closely shows how you feel about birth control (contraception) in general.

62. Embarrassing to discuss ☐ ☐ ☐ ☐ ☐ ☐ ☐ Easy to discuss
63. Make love making better ☐ ☐ ☐ ☐ ☐ ☐ ☐ Spoil love making
64. Easy to use correctly ☐ ☐ ☐ ☐ ☐ ☐ ☐ Hard to use correctly
65. Easy to use every time ☐ ☐ ☐ ☐ ☐ ☐ ☐ Hard to use every time
66. Expensive ☐ ☐ ☐ ☐ ☐ ☐ ☐ Cheap
67. Reduce sexual pleasure ☐ ☐ ☐ ☐ ☐ ☐ ☐ Enhance sexual pleasure
68. Builds trust with partner ☐ ☐ ☐ ☐ ☐ ☐ ☐ Destroys trust with partner
69. Easy to get ☐ ☐ ☐ ☐ ☐ ☐ ☐ Embarrassing to get
70. My health care provider thinks that I should use birth control to prevent an unintentional pregnancy.
- Strongly Agree Agree Unsure Disagree Strongly Disagree
71. My friends think it is important to use birth control to prevent an unintentional pregnancy.
- Strongly Agree Agree Unsure Disagree Strongly Disagree

If you have never had sexual intercourse, go to question number 82.

Health Needs of Enlisted Army and Navy Women

72. In general, what is your current (or most recent) sexual partner's attitude toward using birth control?

Very
Positive

Positive

Neutral

Negative

Very
Negative

Put an X in the box that most closely shows how your current (or most recent) sexual partner feels about birth control.

73. Embarrassing to discuss

--	--	--	--	--	--	--	--

Easy to discuss

74. Improve love making

--	--	--	--	--	--	--	--

Spoil love making

75. Easy to use

--	--	--	--	--	--	--	--

Hard to use

76. Reduces sexual pleasure

--	--	--	--	--	--	--	--

Enhances sexual pleasure

77. Easy to use every time

--	--	--	--	--	--	--	--

Hard to use every time

78. Builds trust

--	--	--	--	--	--	--	--

Destroys trust

79. I am confident that I can correctly use birth control to prevent pregnancy.

Strongly
Agree

Agree

Unsure

Disagree

Strongly
Disagree

80. I am confident that I can use birth control to prevent pregnancy every time I have intercourse.

Strongly
Agree

Agree

Unsure

Disagree

Strongly
Disagree

81. I am confident that I can use birth control to prevent pregnancy if I have been drinking alcohol or using drugs.

Strongly
Agree

Agree

Unsure

Disagree

Strongly
Disagree

Health Needs of Enlisted Army and Navy Women

V. Practices—The following questions ask about your sexual behavior, alcohol, and cigarette use. As we noted earlier, these types of questions often make people uncomfortable. Many people feel the need to give an answer that may be different from what they actually do. Please answer the following questions honestly so that we can find out the important health needs of enlisted Army and Navy women.

The next three questions ask about cigarette smoking.

82. Have you ever smoked cigarettes regularly, that is, at least one cigarette every day for 30 days?

☐ Yes
☐ No

83. During the past 30 days, on how many days did you smoke cigarettes?

☐ 0 days
☐ 1 or 2 days
☐ 3 to 5 days
☐ 6 to 9 days
☐ 10 to 19 days
☐ 20 to 29 days
☐ All 30 days

84. During the past 30 days, on the days you smoked, how many cigarettes did you smoke per day?

☐ I did not smoke cigarettes during the past 30 days
☐ Less than 1 cigarette per day
☐ 1 cigarette per day
☐ 2 to 5 cigarettes per day
☐ 6 to 10 cigarettes per day
☐ 11 to 20 cigarettes per day
☐ More than 20 cigarettes per day

The next three questions ask about drinking alcohol. This includes drinking beer, wine, wine coolers, and liquor such as rum, gin, vodka, or whiskey. For these questions, drinking alcohol does not include drinking a few sips of wine for religious purposes.

85. How old were you when you had your first drink of alcohol other than a few sips?

☐ I have never had a drink of alcohol
☐ 12 years old or younger
☐ 13 or 14 years old
☐ 15 or 16 years old
☐ 17 or 18 years old
☐ 19 or 20 years old
☐ 21 to 24 years old
☐ 25 years old or older

86. During the past 30 days, on how many days did you have at least one drink of alcohol?

☐ 0 days
☐ 1 or 2 days
☐ 3 to 5 days
☐ 6 to 9 days
☐ 10 to 19 days
☐ 20 to 29 days
☐ All 30 days

87. During the past 30 days, on how many days did you have 5 or more drinks of alcohol within a couple-of hours?

☐ 0 days
☐ 1 day
☐ 2 days
☐ 3 to 5 days
☐ 6 to 9 days
☐ 10 to 19 days
☐ 20 or more days

Health Needs of Enlisted Army and Navy Women

The next 12 questions ask about sexual behavior. For this survey, sexual intercourse is defined as vaginal intercourse, anal intercourse, or oral sex.

88. How old were you when you had sexual intercourse for the first time?

- ☐ I have never had sexual intercourse
- ☐ 12 years old or younger
- ☐ 13 or 14 years old
- ☐ 15 or 16 years old
- ☐ 17 or 18 years old
- ☐ 19 or 20 years old
- ☐ 21 or 24 years old
- ☐ 25 years old or older

89. With how many different partners have you had vaginal sex (intercourse) in your lifetime?

- ☐ 0
- ☐ 1
- ☐ 2-3
- ☐ 4-5
- ☐ 6-10
- ☐ 11-20
- ☐ More than 21

90. With how many different partners have you had oral sex (intercourse) in your lifetime?

- ☐ 0
- ☐ 1
- ☐ 2-3
- ☐ 4-5
- ☐ 6-10
- ☐ 11-20
- ☐ More than 21

91. With how many different partners have you had anal sex (intercourse) in your lifetime?

- ☐ 0
- ☐ 1
- ☐ 2-3
- ☐ 4-5
- ☐ 6-10
- ☐ 11-20
- ☐ More than 21

92. How many people have forced you to have sex against your will?

- ☐ 0
- ☐ 1
- ☐ 2
- ☐ 3
- ☐ 4
- ☐ 5 or more

93. What best describes your sexual activity within the past six months?

- ☐ Abstinent/celibate (no intercourse)
- ☐ One long-term "steady" sexual relationship (boyfriend or girlfriend)
- ☐ More than one "steady" relationship
- ☐ One "casual," non-steady sexual relationship
- ☐ More than one "casual" partner
- ☐ One or more "steady" relationship(s) and one or more "casual" partner(s)

94. How many times did you have sexual intercourse in the past 30 days?

- ☐ 0 times
- ☐ 1 time
- ☐ 2 or 3 times
- ☐ 4 to 9 times
- ☐ 10 to 19 times
- ☐ 20 or more times

95. The last time you had sexual intercourse, what birth control method did you use? (Check all that apply.)

- ☐ No method
- ☐ Withdrawal
- ☐ Birth control pills
- ☐ Norplant
- ☐ Depo-Provera
- ☐ Diaphragm
- ☐ Male condom (latex or polyurethane)
- ☐ Male condom (natural)
- ☐ Female condom
- ☐ Spermicide (foam, film, etc.)
- ☐ Tubal ligation
- ☐ Vasectomy
- ☐ Other: _____
- ☐ I have never had sexual intercourse.

Health Needs of Enlisted Army and Navy Women

96. During the past 30 days, how often did you and your partner(s) use a condom?

- ☐ I did not have sexual intercourse during the past 30 days
- ☐ Never used a condom
- ☐ Rarely used a condom
- ☐ Sometimes used a condom
- ☐ Most of the time used a condom
- ☐ Always used a condom

97. Did you drink alcohol or use drugs before you had sexual intercourse the last time?

- ☐ Yes
- ☐ No

98. Do you use a birth control method **every time** you have intercourse? **(Check the one best answer.)**

- ☐ No, and I do not intend to.
- ☐ No, but I intend to start soon.
- ☐ No, but I intend to start within the next 30 days.
- ☐ Yes, and I have been for less than 6 months.
- ☐ Yes, and I have been for more than 6 months.
- ☐ I've never had intercourse, and I do not intend to use birth control when I do.
- ☐ I've never had intercourse, but I intend to use birth control when I do.

99. Do you use an STD prevention method (e.g., condom) **every time** you have intercourse? **(Check the one best answer.)**

- ☐ No, and I do not intend to.
- ☐ No, but I intend to start soon.
- ☐ No, but I intend to start within the next 30 days.
- ☐ Yes, and I have been for less than 6 months.
- ☐ Yes, and I have been for more than 6 months.
- ☐ I've never had intercourse, and I do not intend to use condoms when I do.
- ☐ I've never had intercourse, but I intend to use condoms when I do.

The following 8 questions ask about your reproductive health history. Please answer honestly.

100. How many times have you been pregnant?

- ☐ I have never been pregnant
- ☐ 1 time
- ☐ 2 times
- ☐ 3 times
- ☐ More than 3 times

101. How many unintentional pregnancies have you had?

- ☐ I have never been pregnant
- ☐ 0, all were planned
- ☐ 1
- ☐ 2
- ☐ 3
- ☐ More than 3

102. How often do you have pelvic exams (including a Pap test)?

- ☐ Never
- ☐ Rarely (once)
- ☐ Occasionally (less than 1 per year)
- ☐ Regularly (once per year)
- ☐ Often (more than 1 per year)

103. Have you ever had an STD?

- ☐ Yes
- ☐ No
- ☐ I don't know

104. Which of the following diagnoses have you had or do you currently have? **(Check all that apply.)**

- ☐ Abnormal Pap test
- ☐ Cervical disease (dysplasia)
- ☐ Chlamydia
- ☐ Gonorrhea (GC)
- ☐ Herpes
- ☐ HIV/AIDS
- ☐ Human Papillomavirus ("genital warts")
- ☐ Pelvic Inflammatory Disease (PID)
- ☐ Syphilis
- ☐ Trichomoniasis
- ☐ Urinary tract infection/Bladder infection
- ☐ Yeast infection
- ☐ None

Health Needs of Enlisted Army and Navy Women

105. How often do you have an OB/GYN examination before deploying?

- ☐ All or nearly all of the time (81-100%)
- ☐ Most of the time (61-80%)
- ☐ About half of the time (41-60%)
- ☐ Some of the time (21-40%)
- ☐ Rarely (1-20%)
- ☐ Never (0%)
- ☐ I have never been deployed.

106. For what reasons have you been **unable** to have an OB/GYN examination before deploying? (Check all that apply.)

- ☐ I have never been deployed.
- ☐ I always have a predeployment exam.
- ☐ No problems/symptoms
- ☐ No time
- ☐ Can't get an appointment
- ☐ Commander did not recommend it
- ☐ Doctor did not recommend it
- ☐ Didn't know I should
- ☐ Other: _____

107. What medical and hygiene supplies do you pack **during predeployment** planning to prepare for your reproductive health needs? (Check all that apply.)

- ☐ None
- ☐ Cotton underwear
- ☐ Oral contraceptive supplies
- ☐ Unscented tampons
- ☐ Scented/deodorant tampons
- ☐ Unscented panty liners
- ☐ Scented/deodorant panty liners
- ☐ Unscented wet-wipes
- ☐ Scented wet-wipes
- ☐ Yeast infection medication
- ☐ Female urinary director
- ☐ Other: _____
- ☐ I have never been deployed.

V. Health Education & Health Services —We are interested in how you feel about the health care and the health education that have received in the military. Please answer honestly.

108. Have you had sex education in either junior high or senior high school?

- ☐ No
- ☐ Yes, one class period
- ☐ Yes, a few class periods
- ☐ Yes, several class periods
- ☐ Yes, at least one semester

109. Which reproductive health topics do you want to know more about? (Check all that apply.)

- ☐ I know all I need to know.
- ☐ Pelvic exams
- ☐ Pregnancy prevention
- ☐ Contraception/birth control
- ☐ STD/HIV prevention
- ☐ Prevention of vaginal infections
- ☐ Personal hygiene
- ☐ Menstrual cycle (period)
- ☐ Other: _____

110. Who do you go to when you want information about your health? (Check all that apply.)

- ☐ Friends
- ☐ Parents
- ☐ Doctor/other health care provider
- ☐ Health educator/instructor
- ☐ Your commanding officer
- ☐ Other: _____

111. Where do you go when you want information about your health? (Check all that apply.)

- ☐ Health center/clinic
- ☐ Pharmacy
- ☐ Health telephone hotline
- ☐ Library/resource books
- ☐ Internet
- ☐ Newspapers/magazines
- ☐ Other: _____

Health Needs of Enlisted Army and Navy Women

112. On which of the following health topics have you ever received **written** information (pamphlets, guides) from the military? **(Check all that apply.)**

- ☐ Alcohol prevention
- ☐ Other drug use prevention
- ☐ Birth control/family planning
- ☐ STD prevention
- ☐ AIDS or HIV infection prevention
- ☐ Prevention of vaginal infections
- ☐ Personal hygiene
- ☐ Assertiveness training
- ☐ None
- ☐ I don't remember.

113. On which of the following health topics have you ever viewed **audio or video** health information in the military? **(Check all that apply.)**

- ☐ Alcohol prevention
- ☐ Other drug use prevention
- ☐ Birth control/family planning
- ☐ STD prevention
- ☐ AIDS or HIV infection prevention
- ☐ Prevention of vaginal infections
- ☐ Personal hygiene
- ☐ Assertiveness training
- ☐ None
- ☐ I don't remember.

114. While in the military, which of the following health topics have you ever learned about using a **computer program**? **(Check all that apply.)**

- ☐ Alcohol prevention
- ☐ Other drug use prevention
- ☐ Birth control/family planning
- ☐ STD prevention
- ☐ AIDS or HIV infection prevention
- ☐ Prevention of vaginal infections
- ☐ Personal hygiene
- ☐ Assertiveness training
- ☐ None
- ☐ I don't remember.

115. On which of the following health topics have you ever taken a class in the military? **(Check all that apply.)**

- ☐ Alcohol prevention
- ☐ Other drug use prevention
- ☐ Birth control/family planning
- ☐ STD prevention
- ☐ AIDS or HIV infection prevention
- ☐ Prevention of vaginal infections
- ☐ Personal hygiene
- ☐ Assertiveness training
- ☐ None
- ☐ I don't remember.

116. Where on your military base did you receive information on health? **(Check all that apply.)**

- ☐ I have never received health information on a military base.
- ☐ Active Duty Medical Clinic/Sick Call
- ☐ Troop Medical Clinic
- ☐ OB/GYN Clinic
- ☐ Preventive Medicine Clinic
- ☐ Family Practice Clinic
- ☐ Family Planning Clinic
- ☐ Hospital
- ☐ Other (Specify): _____

117. From whom did you receive health information while in the military? **(Check all that apply.)**

- ☐ Corpsman/medic
- ☐ Community health nurse
- ☐ Nurse
- ☐ Physician assistant (PA)
- ☐ Gynecologist
- ☐ Preventive medicine doctor
- ☐ Civilian doctor
- ☐ Unit leader
- ☐ Commander
- ☐ Other (Specify): _____

118. How **helpful** is the **contraceptive education** enlisted women receive?

- ☐ Very helpful
- ☐ Helpful
- ☐ Moderately helpful
- ☐ Somewhat helpful
- ☐ Not helpful at all

Health Needs of Enlisted Army and Navy Women

119. How would you rate the **amount of contraceptive education** enlisted women receive:

- ☐ Too much
- ☐ A lot
- ☐ Average amount
- ☐ Some
- ☐ Too little

120. How helpful is the **STD prevention education** enlisted women receive?

- ☐ Very helpful
- ☐ Helpful
- ☐ Moderately helpful
- ☐ Somewhat helpful
- ☐ Not helpful at all

121. How would you rate the **amount of STD prevention education** enlisted women receive:

- ☐ Too much
- ☐ A lot
- ☐ Average amount
- ☐ Some
- ☐ Too little

122. How helpful is the **personal hygiene education** enlisted women receive?

- ☐ Very helpful
- ☐ Helpful
- ☐ Moderately helpful
- ☐ Somewhat helpful
- ☐ Not helpful at all

123. How would you rate the **amount of personal hygiene education** enlisted women receive:

- ☐ Too much
- ☐ A lot
- ☐ Average amount
- ☐ Some
- ☐ Too little

124. Do you have a health care provider who you are assigned to see for OB/GYN care visits?

- ☐ Yes
- ☐ No

125. When you have routine OB/GYN care, where do you usually go?

- ☐ Active Duty Medical Clinic/Sick Call
- ☐ OB/GYN Clinic
- ☐ Family Practice Clinic
- ☐ Family Planning Clinic
- ☐ Civilian doctor/clinic
- ☐ Other (Specify): _____
- ☐ I do not have routine OB/GYN care

126. Have you ever visited a military medical facility for routine OB/GYN care?

- ☐ Yes
- ☐ No

If NO, go to question 131.

127. Who provided **most** of your care during routine OB/GYN visits at a military medical facility? (Select only one.)

- ☐ Not sure.
- ☐ Medical Corpsman
- ☐ Technician
- ☐ Nurse
- ☐ Nurse Practitioner
- ☐ Physician Assistant
- ☐ Physician
- ☐ Other (Specify): _____

128. When you get reproductive health care, how likely is it that you are able to see the same health care provider?

- ☐ Definitely (100%)
- ☐ Very likely (81-99% of the time)
- ☐ Likely (61-80% of the time)
- ☐ Somewhat likely (41-60% of the time)
- ☐ Unlikely (21-40% of the time)
- ☐ Very unlikely (1-20% of the time)
- ☐ Not likely at all (0%)

Health Needs of Enlisted Army and Navy Women

129. For your last (or only) OB/GYN visit, do you believe you were given priority over non-active duty people **when arranging for the visit?**

- ☐ Yes
☐ No
☐ Don't know

130. For your last (or only) OB/GYN visit, do you believe you were given priority over non-active duty people **at the time of the visit?**

- ☐ Yes
☐ No
☐ Don't know

Put an X in the box that most closely shows how you feel about military medical care in general.

131.

Very Positive

--	--	--	--	--	--	--	--

Very Negative

132.

Low Quality

--	--	--	--	--	--	--	--

High Quality

133.

Easy to get appointments

--	--	--	--	--	--	--	--

Hard to get appointments

134.

Slow to get test results

--	--	--	--	--	--	--	--

Quick to get test results

135.

Confidential

--	--	--	--	--	--	--	--

Not confidential

136.

Competent staff

--	--	--	--	--	--	--	--

Incompetent staff

137.

Too little time with doctor

--	--	--	--	--	--	--	--

Too much time with doctor

138.

Hard to talk to doctor

--	--	--	--	--	--	--	--

Easy to talk to doctor

139.

Short wait for appointment

--	--	--	--	--	--	--	--

Long wait for appointment

140. If you had a reproductive health problem (suspected pregnancy or STD, etc.), where would you go for care? **(Select only one answer.)**

- ☐ Active Duty Medical Clinic/Sick Call
☐ OB/GYN Clinic
☐ Family Practice Clinic

- ☐ Family Planning Clinic
☐ Civilian doctor/clinic
☐ Other (Specify): _____

Appendix D

**Invitation Letter
for Military Health Care Provider
Needs Assessment**

Date

Address

Re: Participation in a study "CD-ROM Technology to Increase Appropriate Self-Care and Preventive Behaviors Among Army and Navy Women"

Civilian Principal Investigator: Dr. Robert S. Gold, Ph.D., Dr.P.H.

Military Principal Investigator: Dr. Evelyn Lewis, M.D.

Dear _____:

Please take the time to complete the enclosed survey which is part of a study to find out the most pressing self-care and preventive education needs of enlisted women concerning their reproductive health. This study is funded by the U.S. Army Medical Research and Materiel Command (USAMRMC). Macro International Inc., a private research/consulting firm, is conducting the research study in conjunction with the Uniformed Services University of the Health Sciences (USUHS). This study is important because the number of women in the U.S. Armed Forces is increasing, and the Department of Defense is concerned about their health needs. The results of the survey will be used to help develop educational materials on reproductive health for enlisted women.

You are one of approximately 260 health care providers in the Army and Navy have been selected from several bases across the country to participate by completing this needs assessment survey. We are also conducting separate needs assessment surveys with enlisted women in the Army and Navy and with chairpersons of military medical departments providing reproductive health care to enlisted women.

Completing the survey is voluntary. Your military record will not be affected if this survey questionnaire is not returned. However, we sincerely hope that you will contribute to this needs assessment of the reproductive health care needs of enlisted women by participating in the survey. Your responses will be safeguarded to the fullest extent possible in accordance with applicable statutes. The identification number on the questionnaire allows us to send a reminder to health care providers who do not return surveys. The names and addresses corresponding to the identification numbers will be kept in a locked file available only to authorized Macro staff. Upon receiving your survey, we will destroy all information that would allow linking your answers with you. Neither U.S. Army nor U.S. Navy staff will be given the information needed to link individual responses with identifying information of any type.

To participate in the study, fill out the survey and return it to the principal investigator in the enclosed prepaid envelope. If you have misplaced the envelope enclosed with the survey, send your completed survey to: DOD Women's Health Survey, Macro International Inc., 126 College Street, Suite 2A, Burlington, VT 05401-9951.

If you have any questions or need any more information about this study, please call Dr. Robert Gold at Macro International Inc. at 1-800-xxx-xxxx. Any questions concerning your rights as a study subject should be directed to James Ross, IRB Chairperson at the same number. We thank you for your time and look forward to your participation in this important study.

Robert Gold, Ph.D., Dr. P.H.
Civilian Principal Investigator

Dr. Evelyn Lewis, CDR. MC, USN-USUHS
Military Principal Investigator

Appendix E

**Military Clinician Survey
Questionnaire**

Health Care Provider Survey: Health Needs of Enlisted Army and Navy Women

The purpose of this survey is to collect information about the health knowledge, attitudes, and practices of military health care providers who serve enlisted Army and Navy women. The information you provide will help to identify the kind of health programs and services enlisted women in the Army and Navy need.

The survey asks several questions about reproductive health care provided to enlisted women. We realize that some of the questions may be sensitive for health care providers who may feel that standard medical care should include some services that they are unable to provide because of constraints. To get good information, it is important that everyone be as honest as possible.

Completing the survey is voluntary, and the answers you give will be safeguarded to the fullest extent possible in accordance with the applicable statutes. Once we receive your survey, we will destroy the information linking your answers with any personal information, so your answers will then be anonymous. Your answers will be combined with the answers of other military health care providers serving enlisted Army and Navy women. No individual responses will be reported, so please answer every question as honestly as you can.

Do not write your name on this survey.

When you are finished, send back the completed survey in the return envelope. No postage is necessary.

Thank you very much for your help.

Health Care Provider Survey: Health Needs of Enlisted Army and Navy Women

I. Demographics—Mark only one answer to each question unless you are asked to check all that apply.

1. How old are you? _____ Years
2. What is your sex?
 - ☐ Female
 - ☐ Male
3. How do you describe yourself?
 - ☐ White—not Hispanic
 - ☐ Black—not Hispanic
 - ☐ Hispanic or Latino
 - ☐ Asian or Pacific Islander
 - ☐ American Indian or Alaskan Native
 - ☐ Other (specify): _____
4. In what branch of the service are you?
 - ☐ Army
 - ☐ Navy
 - ☐ Air Force
 - ☐ Other (Specify): _____
5. Date of entry in the service:
Month _____ Day _____ Year _____
6. Date of separation/Estimated time of separation
Month _____ Day _____ Year _____
7. Type of health care provider:
 - ☐ Nurse
 - ☐ Nurse Practitioner
 - ☐ Physician's Assistant
 - ☐ Physician
 - ☐ Other (Specify): _____
8. Type of clinic/service where you practice:
 - ☐ Family Practice
 - ☐ Internal Medicine
 - ☐ Obstetrics/Gynecology
 - ☐ Preventive Medicine
 - ☐ Primary Care
 - ☐ Other (Specify): _____
9. In what year did you complete your medical training (e.g., medical/nursing school, etc.)?
19 ____
10. In what type of health care facility did you receive your postgraduate medical/nursing training?
 - ☐ Military
 - ☐ Civilian
11. Have you had training in health care as it pertains to readiness?
 - ☐ Yes
 - ☐ No
12. What type of deployment experience do you have? (Select all that apply.)
 - ☐ None
 - ☐ Field training exercises
 - ☐ Combat duty
 - ☐ Humanitarian missions
 - ☐ Other (Specify): _____
13. Prior to this study have you ever had any training in **women's health**? Please do not count participation in this study. (Select all that apply.)
 - ☐ None, and I am not interested in any
 - ☐ None, but I would like to have training in this area.
 - ☐ Medical/nursing school
 - ☐ Residency
 - ☐ Subspecialty certification
 - ☐ Continuing medical education
 - ☐ Other (Specify): _____

Health Care Provider Survey: Health Needs of Enlisted Army and Navy Women

14. Prior to this study have you ever had any training in **STD prevention counseling** skills? (Select all that apply.)

- ☐ None, and I am not interested in any
- ☐ None, but I would like to have training in this area.
- ☐ Medical/nursing school
- ☐ Residency
- ☐ Subspecialty certification
- ☐ Continuing medical education
- ☐ Other (Specify): _____

15. Prior to this study have you ever had any training in **sexual risk assessment** (sexual history taking) skills? (Select all that apply.)

- ☐ None, and I am not interested in any
- ☐ None, but I would like to.
- ☐ Medical/nursing school
- ☐ Residency
- ☐ Subspecialty certification
- ☐ Continuing medical education
- ☐ Other (Specify): _____

16. Prior to this study have you ever had any training in **contraception counseling** skills? (Select all that apply.)

- ☐ None, and I am not interested in any
- ☐ None, but I would like to.
- ☐ Medical/nursing school
- ☐ Residency
- ☐ Subspecialty certification
- ☐ Continuing medical education
- ☐ Other (Specify): _____

If you are not a physician, GO TO QUESTION #20.

For Physicians:

17. In which of the following specialties are you board certified or board eligible? (Select all that apply.)

- ☐ Family Practice
- ☐ Internal Medicine
- ☐ Obstetrics/Gynecology
- ☐ None, I am a General Medical Officer.
- ☐ I am not a physician
- ☐ Other (Specify): _____

18. In which type of health care facility did you do your internship?

- ☐ Military
- ☐ Civilian

19. In which type of health care facility did you do your residency?

- ☐ Military
- ☐ Civilian
- ☐ None, I am a General Medical Officer

Health Care Provider Survey: Health Needs of Enlisted Army and Navy Women

II. Knowledge—Read each of the following questions, and select the answers you think are correct. It is important that we find out what women do and do not know, so please do not discuss your answers with anyone or ask anyone for help in answering the questions. You are not expected to know all the correct answers. Mark only one answer for each question.

20. When does the ovulation phase of the female reproductive cycle usually occur?
- ☐ Right before a woman's period
 - ☐ During a woman's period
 - ☐ Right after a woman's period
 - ☐ Mid-cycle
 - ☐ I don't know
21. What is the best method for cleaning the vagina?
- ☐ Using vinegar and water douche
 - ☐ Using vaginal deodorants
 - ☐ Letting normal secretions cleanse the vagina
 - ☐ Using Deodorant soap
 - ☐ I don't know
22. Which is the best way to clean the vagina in the field?
- ☐ With scented deodorant sprays
 - ☐ With disposable wipes
 - ☐ By drinking plenty of water
 - ☐ There is no way to be clean in the field.
 - ☐ I don't know
23. How can a woman be relatively sure she has **NO** STDs?
- ☐ When she has no symptoms of itching or burning
 - ☐ When she has a normal Pap test
 - ☐ When her doctor does not notice any problems
 - ☐ When screening tests show no infection
 - ☐ I don't know
24. Which of the following is most responsible for contraceptive failure among American women?
- ☐ User error by either partner
 - ☐ Faulty devices
 - ☐ Lack of directions
 - ☐ Poor selection of method
 - ☐ I don't know
25. Which of the following is an effective method of birth control?
- ☐ Condoms
 - ☐ Withdrawal
 - ☐ Calendar method (rhythm)
 - ☐ Douching
 - ☐ I don't know
26. At what point in the monthly reproductive cycle can a woman **most** likely become pregnant?
- ☐ Just after period (menstrual phase)
 - ☐ Just before period (menstrual phase)
 - ☐ Within one day of ovulation
 - ☐ Four days after ovulation
 - ☐ I don't know

Health Care Provider Survey: Health Needs of Enlisted Army and Navy Women

For the following questions, check whether the statements that finish the phrase are true or false. If you do not know the answer, circle, "Don't know."

27. What should enlisted women do to prepare for deployment?

- | | | | |
|---|------|-------|------------|
| a. Have an OB/GYN exam | True | False | Don't Know |
| b. Have a pregnancy test | True | False | Don't Know |
| c. Stop using birth control | True | False | Don't Know |
| d. Pack plenty of personal hygiene supplies | True | False | Don't Know |

28. Being assertive in sexual matters means:

- | | | | |
|--|------|-------|------------|
| a. Taking responsibility for protection against disease and pregnancy | True | False | Don't Know |
| b. Relying solely on your partner to be responsible for protection against disease and pregnancy | True | False | Don't Know |
| c. Saying no to a partner when necessary | True | False | Don't Know |
| d. Talking with a partner about sex | True | False | Don't Know |

29. Sexually transmitted diseases (STDs) can lead to all the following health problems:

- | | | | |
|--------------------------------------|------|-------|------------|
| a. Premenstrual syndrome (PMS) | True | False | Don't Know |
| b. Cervical cancer | True | False | Don't Know |
| c. Infertility/sterility | True | False | Don't Know |
| d. Pelvic inflammatory disease (PID) | True | False | Don't Know |
| e. Endometriosis | True | False | Don't Know |

30. The risk of an STD infection is increased by:

- | | | | |
|--|------|-------|------------|
| a. Having many steady boyfriends with whom one has had sex | True | False | Don't Know |
| b. Having sex when drunk or high | True | False | Don't Know |
| c. Having sex when unclean | True | False | Don't Know |
| d. Having sex without a barrier method, such as condoms | True | False | Don't Know |

31. A woman can minimize sexual health problems in the field by:

- | | | | |
|---|------|-------|------------|
| a. Using condoms if any sexual contact occurs | True | False | Don't Know |
| b. Cleaning genitals with scented products | True | False | Don't Know |
| c. Wearing cotton underwear | True | False | Don't Know |
| d. Cleaning genitals with water | True | False | Don't Know |

Health Care Provider Survey: Health Needs of Enlisted Army and Navy Women

32. Enlisted women who become pregnant are more likely to experience:

- | | | | |
|---|------|-------|------------|
| a. Mandatory discharge from the military | True | False | Don't Know |
| b. Fewer career/advancement opportunities | True | False | Don't Know |
| c. Avoidance of field duty | True | False | Don't Know |
| d. Avoidance of physical training (PT) | True | False | Don't Know |
| e. Place on non-deployable status | True | False | Don't Know |
| f. Harassment from peers/commander | True | False | Don't Know |
| g. Light duty assignment | True | False | Don't Know |

33. Yeast infections are **more common** among women who:

- | | | | |
|-----------------------------|------|-------|------------|
| a. Are pregnant | True | False | Don't Know |
| b. Have diabetes | True | False | Don't Know |
| c. Take birth control pills | True | False | Don't Know |
| d. Do not douche | True | False | Don't Know |
| e. Use antibiotics | True | False | Don't Know |

III. Attitudes—The following questions ask your opinion about specific health problems and behaviors that are important for enlisted Army and Navy women.

34. **Ideally**, which of the following *should be included in routine care visits* for enlisted women for their reproductive health? **(Select all that apply.)**

- ☐ Pregnancy testing
- ☐ Contraceptive education/counseling
- ☐ STD screening
- ☐ Sexual history taking
- ☐ STD prevention education
- ☐ Education on hygiene practices
- ☐ None.
- ☐ Other (Specify): _____

35. **Realistically**, which of the following *are being included in routine care visits* for enlisted women for their reproductive health? **(Select all that apply.)**

- ☐ Pregnancy testing
- ☐ Contraceptive education/counseling
- ☐ STD screening
- ☐ Sexual history taking
- ☐ STD prevention education
- ☐ Education on hygiene practices
- ☐ None.
- ☐ Other (Specify): _____
- ☐ I don't know.

36. **Ideally**, which of the following should be included in **predeployment care** for enlisted women for their reproductive health? **(Select all that apply.)**

- ☐ Pregnancy testing
- ☐ Contraceptive education/counseling
- ☐ STD prevention education
- ☐ Prescription medication review
- ☐ Education on hygiene practices
- ☐ None
- ☐ Other (Specify): _____

37. **Realistically**, which of the following are included in **predeployment care** for enlisted women for their reproductive health? **(Select all that apply.)**

- ☐ Pregnancy testing
- ☐ Contraceptive education/counseling
- ☐ STD prevention education
- ☐ Prescription medication review
- ☐ Education on hygiene practices
- ☐ None
- ☐ Other (Specify): _____
- ☐ I don't know.

Health Care Provider Survey: Health Needs of Enlisted Army and Navy Women

38. Ideally, what medical and hygiene supplies would you **recommend be available** during deployment to care for the reproductive health needs of enlisted women? (Select all that apply.)

☐ None.
☐ Oral contraceptives
☐ Depo Provera injections
☐ Condoms
☐ Unscented tampons
☐ Unscented panty liners
☐ Unscented wet-wipes
☐ Yeast infection medication
☐ Female urinary director
☐ Other: _____

39. In your experience, what is the **most common** reproductive health problem among enlisted women? (Select one.)

☐ STD infection
☐ Unintended pregnancy
☐ Ectopic pregnancy
☐ Spontaneous abortion
☐ Vaginal infection (non-STD)
☐ Urinary tract infection
☐ Other: _____

40. In your experience, what is the **most serious** reproductive health problem among enlisted women?

☐ STD infection
☐ Unintended pregnancy
☐ Spontaneous abortion
☐ Ectopic pregnancy
☐ Yeast infection
☐ Urinary tract infection
☐ Other: _____

41. In your experience, what is the **most common** reproductive health problem among enlisted women in the field?

☐ STD infection
☐ Unintended pregnancy
☐ Spontaneous abortion
☐ Ectopic pregnancy
☐ Vaginal infection (non-STD)
☐ Urinary tract infection
☐ Other: _____
☐ No field experience with women

42. In your experience, what is the **most serious** reproductive health problem among enlisted women in the field?

☐ STD infection
☐ Unintended pregnancy
☐ Spontaneous abortion
☐ Ectopic pregnancy
☐ Yeast infection
☐ Urinary tract infection
☐ Other: _____
☐ No field experience with women

43. In your experience, what is the **most common reason for premature separation** from the military among enlisted women?

☐ Exceeding height/weight/body fat standards
☐ Drug/alcohol abuse
☐ Criminal activity
☐ Physical disability/injury
☐ Pregnancy
☐ Other: _____

44. What is the likelihood that the average enlisted woman will experience an STD within the next year?

☐ Very likely
☐ Likely
☐ Unsure
☐ Unlikely
☐ Very Unlikely

45. What is the likelihood that the average enlisted woman will experience an **unintentional pregnancy** within the next year?

☐ Very likely
☐ Likely
☐ Unsure
☐ Unlikely
☐ Very unlikely

Health Care Provider Survey: Health Needs of Enlisted Army and Navy Women

46. What is the likelihood that the average enlisted woman will experience a vaginal infection (non-STD) within the next year?

- ☐ Very likely
- ☐ Likely
- ☐ Unsure
- ☐ Unlikely
- ☐ Very unlikely

47. In general, what is the attitude of enlisted women toward **using condoms**?

- ☐ Very positive
- ☐ Positive
- ☐ Neutral
- ☐ Negative
- ☐ Very negative
- ☐ I don't know.

48. In general, what is the attitude of enlisted women toward **using a method of birth control**?

- ☐ Very positive
- ☐ Positive
- ☐ Neutral
- ☐ Negative
- ☐ Very negative
- ☐ I don't know.

49. What is the most common reason that enlisted women have **unintentional pregnancies**? (Select one answer.)

- ☐ Lack of knowledge about reproduction
- ☐ Lack of skill using birth control
- ☐ Inability to persuade partner to use birth control method
- ☐ Not feeling that she is at risk
- ☐ Lack of awareness of effect on life
- ☐ Negative attitudes toward birth control
- ☐ Religious reasons
- ☐ Partner's negative attitudes toward birth control
- ☐ Strategy to avoid field duty
- ☐ Other: _____
- ☐ I don't know.

50. What is the most common reason that enlisted women **do not use safer sex practices**? (Select one answer.)

- ☐ Lack of knowledge about STDs
- ☐ Lack of skill using condoms
- ☐ Inability to persuade partner to use STD prevention method
- ☐ Not feeling that she is at risk
- ☐ Low self-esteem
- ☐ Negative attitudes toward condoms
- ☐ Religious reasons
- ☐ Partner's negative attitudes toward
- ☐ Other: _____
- ☐ I don't know.

51. What is the most common reason that enlisted women get **non-STD vaginal infections** (yeast, etc.)? (Select one answer.)

- ☐ Lack of knowledge about hygiene
- ☐ Improper use of hygiene products
- ☐ Unhealthy lifestyle (stress, poor diet)
- ☐ Lack of skill in proper hygiene
- ☐ Inability to practice proper hygiene in the field environment
- ☐ Not feeling that she is at risk
- ☐ Other: _____
- ☐ I don't know.

Health Care Provider Survey: Health Needs of Enlisted Army and Navy Women

IV. Health Services—The next questions are about services you may provide to enlisted women during routine health visits (annual Pap test), during predeployment, and during deployment. We realize that health care providers often have "ideal" standards but that they may not be able to deliver their "ideal" health care due to different constraints. We are interested in what you are able to do.

The following 11 questions are about routine care visits.

52. What proportion of your patients are enlisted women?
- ☐ All or nearly all (81-100%)
 - ☐ Most (61-80%)
 - ☐ About half (41-60%)
 - ☐ Some (21-40%)
 - ☐ Few (1-20%)
 - ☐ None (0%)
53. What proportion of your enlisted female patients do you provide with **contraceptive counseling and education**?
- ☐ All or nearly all (81-100%)
 - ☐ Most (61-80%)
 - ☐ About half (41-60%)
 - ☐ Some (21-40%)
 - ☐ Few (1-20%)
 - ☐ None (0%)
54. What proportion of your enlisted female patients do you provide with **STD prevention counseling and education**?
- ☐ All or nearly all (81-100%)
 - ☐ Most (61-80%)
 - ☐ About half (41-60%)
 - ☐ Some (21-40%)
 - ☐ Few (1-20%)
 - ☐ None (0%)
55. On what proportion of your enlisted female patients do you take a **sexual history (sexual risk assessment)**?
- ☐ All or nearly all (81-100%)
 - ☐ Most (61-80%)
 - ☐ About half (41-60%)
 - ☐ Some (21-40%)
 - ☐ Few (1-20%)
 - ☐ None (0%)
56. What proportion of your enlisted female patients do you personally ask about their **use of STD prevention methods**?
- ☐ All or nearly all (81-100%)
 - ☐ Most (61-80%)
 - ☐ About half (41-60%)
 - ☐ Some (21-40%)
 - ☐ Few (1-20%)
 - ☐ None (0%)
57. What proportion of your enlisted female patients do you provide with information on **personal hygiene**?
- ☐ All or nearly all (81-100%)
 - ☐ Most (61-80%)
 - ☐ About half (41-60%)
 - ☐ Some (21-40%)
 - ☐ Few (1-20%)
 - ☐ None (0%)
58. What prevents you from providing ***routine* contraceptive counseling and education** to your enlisted female patients? (Select all that apply.)
- ☐ I provide this service to all patients.
 - ☐ I only provide this service to patients who request it.
 - ☐ Not needed by all patients
 - ☐ No time
 - ☐ Lack of staff
 - ☐ Lack of skills
 - ☐ Lack of comfort
 - ☐ No policy making this standard care
 - ☐ Not effective
 - ☐ Other: _____

Health Care Provider Survey: Health Needs of Enlisted Army and Navy Women

59. What prevents you from taking a **sexual history** (sexual risk assessment) from your enlisted female patients? (Select all that apply.)

- ☐ I provide this service to all patients.
- ☐ I only provide this service to patients who request it.
- ☐ Not needed by all patients
- ☐ No time
- ☐ Lack of staff
- ☐ Lack of skills
- ☐ Lack of comfort
- ☐ No policy making this standard care
- ☐ Not effective
- ☐ Other: _____

60. What prevents you from providing **STD prevention counseling and education** to your enlisted female patients? (Select all that apply.)

- ☐ I provide this service to all patients.
- ☐ I only provide this service to patients who request it.
- ☐ Not needed by all patients
- ☐ No time
- ☐ Lack of staff
- ☐ Lack of skills
- ☐ Lack of comfort
- ☐ No policy making this standard care
- ☐ Not effective
- ☐ Other: _____

61. What prevents you from asking enlisted female patients about their use of **STD prevention methods**? (Select all that apply.)

- ☐ I provide this service to all patients.
- ☐ I only provide this service to patients who request it.
- ☐ Not needed by all patients
- ☐ No time
- ☐ Lack of staff
- ☐ Lack of skills
- ☐ Lack of comfort
- ☐ No policy making this standard care
- ☐ Not effective
- ☐ Other: _____

62. What prevents you from providing **personal hygiene information** to enlisted female patients? (Select all that apply.)

- ☐ I provide this service to all patients.
- ☐ I only provide this service to patients who request it.
- ☐ Not needed by all patients
- ☐ No time
- ☐ Lack of staff
- ☐ Lack of skills
- ☐ Lack of comfort
- ☐ No policy making this standard care
- ☐ Not effective
- ☐ Other: _____

The following 5 questions refer to care given to enlisted women during predeployment.

63. What proportion of your enlisted female patients do you see for a **predeployment** medical appointment?

- ☐ All or nearly all (81-100%)
- ☐ Most (61-80%)
- ☐ About half (41-60%)
- ☐ Some (21-40%)
- ☐ Few (1-20%)
- ☐ None (0%)
- ☐ I am not responsible for predeployment care.

64. What do you do to prepare enlisted female patients for their reproductive health needs **during predeployment planning**? (Select all that apply.)

- ☐ Pregnancy testing
- ☐ Contraceptive education/counseling
- ☐ STD prevention education
- ☐ Prescription medication review
- ☐ Education on hygiene practices
- ☐ None
- ☐ Other: _____
- ☐ I am not responsible for predeployment care.

Health Care Provider Survey: Health Needs of Enlisted Army and Navy Women

65. What prevents you from providing **predeployment contraceptive education and counseling** to enlisted female patients? (Select all that apply.)

- ☐ I provide this service to all patients.
- ☐ Not needed by all patients
- ☐ No time
- ☐ Lack of staff
- ☐ Lack of skills
- ☐ Lack of comfort
- ☐ No policy making this standard care.
- ☐ Not effective
- ☐ Other: _____
- ☐ I am not responsible for predeployment care.

66. What prevents you from providing **personal hygiene information** to enlisted female patients during predeployment planning? (Select all that apply.)

- ☐ I provide this service to all patients.
- ☐ Not needed by all enlisted women
- ☐ No time
- ☐ Lack of staff
- ☐ Lack of skills
- ☐ No policy making this standard care.
- ☐ Not effective
- ☐ Other: _____

67. What prevents you from providing **STD prevention counseling** and education to enlisted female patients during **predeployment planning**? (Select all that apply.)

- ☐ I provide this service to all patients.
- ☐ Not needed by all enlisted women
- ☐ No time
- ☐ Lack of staff
- ☐ Lack of skills
- ☐ No policy making this standard care.
- ☐ Not effective
- ☐ Other: _____

The next 4 questions ask about care you have given to enlisted women during deployment.

68. What do you do to educate **individual** enlisted female patients about their reproductive health needs **during deployment**? (Select all that apply.)

- ☐ Contraceptive education/counseling
- ☐ STD prevention education
- ☐ Education on hygiene practices
- ☐ None
- ☐ Other: _____
- ☐ I have not participated in a deployment with women.

69. What do you do to educate enlisted female patients **as a group** about their reproductive health needs **during deployment**? (Select all that apply.)

- ☐ Contraceptive education/counseling
- ☐ STD prevention education
- ☐ Education on hygiene practices
- ☐ None
- ☐ Other: _____
- ☐ I have not participated in a deployment with women.

70. What do you do when treating enlisted female patients with their reproductive health needs **during deployment**? (Select all that apply.)

- ☐ Sexual history taking
- ☐ Pregnancy testing
- ☐ Contraceptive education/counseling
- ☐ STD prevention education
- ☐ Education on hygiene practices
- ☐ Treatment of acute infection
- ☐ Dispense oral contraceptive
- ☐ None
- ☐ Other: _____
- ☐ I have not participated in a deployment with women.

71. What medical and hygiene supplies are **routinely available** to you during deployment to care for the reproductive health needs of enlisted women? (Select all that apply.)

- ☐ I am not responsible for OB/GYN deployment care.
- ☐ Oral contraceptives
- ☐ Depo Provera injections
- ☐ Condoms
- ☐ Unscented tampons
- ☐ Unscented panty liners
- ☐ Unscented wet-wipes
- ☐ Yeast infection medication
- ☐ Female urinary director
- ☐ Other: _____

Health Care Provider Survey: Health Needs of Enlisted Army and Navy Women

Put an X in the box that most closely shows your opinion about the medical care enlisted women receive in the military.

72. Very Positive ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ Very Negative
73. Low Quality ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ High Quality
74. Easy to get appointments ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ Hard to get appointments
75. Overdue test results ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ Timely test results
76. Confidential ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ Not confidential
77. Competent staff ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ Incompetent staff
78. Inadequate time with clinician ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ Adequate time with clinician
79. Hard to talk to clinician ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ Easy to talk to clinician

V. Health Education—We are interested in how you feel about the health education that enlisted women receive in the military in general. Please answer the following questions:

80. On which reproductive health topics have you ever given a class (or presentation) to enlisted female patients? **(Select all that apply.)**

- ☐ Alcohol and other drug use prevention
- ☐ Birth control/family planning
- ☐ STD prevention
- ☐ AIDS or HIV infection prevention
- ☐ Prevention of vaginal infections
- ☐ Personal hygiene
- ☐ Empowerment/assertiveness training
- ☐ I have never presented information on any of these topics to enlisted women.

81. Which **written** health education materials have you given to enlisted female patients about their health? **(Select all that apply.)**

- ☐ Alcohol and other drug use prevention
- ☐ Birth control/family planning
- ☐ STD prevention
- ☐ AIDS or HIV infection prevention
- ☐ Prevention of vaginal infections
- ☐ Empowerment/assertiveness training
- ☐ Personal hygiene
- ☐ I have never given written information on these topics to enlisted women.

Health Care Provider Survey: Health Needs of Enlisted Army and Navy Women

82. Which **video/audio** health education materials have you used to teach enlisted female patients about their health? (**Select all that apply.**)

- ☐ Alcohol and other drug use prevention
- ☐ Birth control/family planning
- ☐ STD prevention
- ☐ AIDS or HIV infection prevention
- ☐ Prevention of vaginal infections
- ☐ Personal hygiene
- ☐ Empowerment/assertiveness training
- ☐ I have never given video or audio information on these topics to enlisted women.

83. Which **computer-based** health education materials have you used to teach enlisted female patients about their health? (**Select all that apply.**)

- ☐ Alcohol and other drug use prevention
- ☐ Birth control/family planning
- ☐ STD prevention
- ☐ AIDS or HIV infection prevention
- ☐ Prevention of vaginal infections
- ☐ Personal hygiene
- ☐ Empowerment/assertiveness training
- ☐ I have never given computer-based information on these topics to enlisted women.

84. Choose the statement that best describes the **quality of contraceptive education** enlisted women receive:

- ☐ Very good
- ☐ Above average
- ☐ Average
- ☐ Below average
- ☐ Very bad

85. Choose the statement that best describes the **amount of contraceptive education** enlisted women receive:

- ☐ Too much
- ☐ A lot
- ☐ Average amount
- ☐ Some
- ☐ Too little

86. Choose the statement that best describes the **quality of STD prevention education** enlisted women receive:

- ☐ Very good
- ☐ Above average
- ☐ Average
- ☐ Below average
- ☐ Very bad

87. Choose the statement that best describes the **amount of STD prevention education** enlisted women receive:

- ☐ Too much
- ☐ A lot
- ☐ Average amount
- ☐ Some
- ☐ Too little

88. Choose the statement that best describes the **quality of personal hygiene education** enlisted women receive:

- ☐ Very good
- ☐ Above average
- ☐ Average
- ☐ Below average
- ☐ Very bad

89. Choose the statement that best describes the **amount of personal hygiene education** enlisted women receive:

- ☐ Too much
- ☐ A lot
- ☐ Average amount
- ☐ Some
- ☐ Too little

Appendix F

**Invitation Letter
for Department Chairperson's
Needs Assessment Survey**

Date

Address

Re: Participation in a study "CD-ROM Technology to Increase Appropriate Self-Care and Preventive Behaviors Among Army and Navy Women"

Civilian Principal Investigator: Dr. Robert S. Gold, Ph.D., Dr.P.H.

Military Principal Investigator: Dr. Evelyn Lewis, M.D.

Dear _____:

Please take the time to complete the enclosed survey which is part of a study to find out the most pressing self-care and preventive education needs of enlisted women concerning their reproductive health. This study is funded by the U.S. Army Medical Research and Materiel Command (USAMRMC). Macro International Inc., a private research/consulting firm, is conducting the research study in conjunction with the Uniformed Services University of the Health Sciences (USUHS). This study is important because the number of women in the U.S. Armed Forces is increasing, and the Department of Defense is concerned about their health needs. The results of the survey will be used to help develop educational materials on reproductive health for enlisted women.

You and approximately 160 other chairpersons of medical departments serving the reproductive needs of enlisted Army and Navy women have been randomly selected from 250 bases across the country to participate by completing this needs assessment survey. We are also surveying enlisted Army and Navy women and the military health care providers.

Completing the survey is voluntary. Your military record will not be affected if this survey questionnaire is not returned. However, we sincerely hope that you will contribute to this needs assessment of the reproductive health care needs of enlisted women by participating in the survey. Your responses will be safeguarded to the fullest extent possible in accordance with applicable statutes. The identification number on the questionnaire allows us to send a reminder to health care providers who do not return surveys. The names and addresses corresponding to the identification numbers will be kept in a locked file available only to authorized Macro staff. Upon receiving your survey, we will destroy all information that would allow linking your answers with you. Neither U.S. Army nor U.S. Navy staff will be given the information needed to link individual responses with identifying information of any type.

To participate in the survey, fill out the survey and return it to the principal investigator in the enclosed prepaid envelope. If you have misplaced the envelope enclosed with the survey, send your completed survey to: DOD Women's Health Survey, Macro International Inc., 126 College Street, Suite 2A, Burlington, VT 05401-9951.

If you have any questions or need any more information about this study, please call Dr. Robert Gold at Macro International Inc. at 1-800-xxx-xxxx. Any questions concerning your rights as a study subject should be directed to James Ross, IRB Chairperson at the same number. We thank you for your time and look forward to your participation in this important study.

Robert Gold, Ph.D., Dr. P.H.
Civilian Principal Investigator

Dr. Evelyn Lewis, CDR. MC, USN-USUHS
Military Principal Investigator

Appendix G

**Chairperson Survey
Questionnaire**

Needs Assessment Survey: Health Education of Enlisted Army and Navy Women

This survey is about health education and health services as they pertain to the reproductive health needs of enlisted women in the U.S. Army and Navy. The information you provide will help identify the kind of health programs and services enlisted women in the Army and Navy need.

Do not write your name or any other identifying information on this survey.

I. Demographics

- | | |
|---|--|
| <p>1. Age: _____ Years</p> <p>2. Sex: <input type="checkbox"/> Female
 <input type="checkbox"/> Male</p> <p>3. Race/Ethnicity:</p> <p><input type="checkbox"/> White - not Hispanic
<input type="checkbox"/> Black - not Hispanic
<input type="checkbox"/> Hispanic or Latino
<input type="checkbox"/> Asian or Pacific Islander
<input type="checkbox"/> American Indian/Alaskan Native
<input type="checkbox"/> Other (specify): _____</p> <p>4. Service Branch:</p> <p><input type="checkbox"/> Army
<input type="checkbox"/> Navy
<input type="checkbox"/> Air Force
<input type="checkbox"/> Other (Specify): _____</p> <p>5. Your title:</p> <p><input type="checkbox"/> Chairperson
<input type="checkbox"/> Troop Clinic Commander
<input type="checkbox"/> Senior Medical Officer
<input type="checkbox"/> Other (Specify): _____</p> <p>6. Department:</p> <p><input type="checkbox"/> Family Practice
<input type="checkbox"/> Obstetrics/Gynecology
<input type="checkbox"/> Preventive Medicine
<input type="checkbox"/> Active Duty Medical Clinic/Sick Call
<input type="checkbox"/> Other (Specify): _____</p> <p>7. Where is your service/department located?</p> <p><input type="checkbox"/> In a teaching medical center
<input type="checkbox"/> In a community hospital
<input type="checkbox"/> In a freestanding clinic
<input type="checkbox"/> Other (Specify): _____</p> <p>8. Year medical training completed:</p> <p>Medical School: 19 ____</p> <p>Residency: 19 ____</p> | <p>9. Have you had training in health care as it pertains to readiness?</p> <p><input type="checkbox"/> Yes
<input type="checkbox"/> No</p> <p>10. What type of deployment experience do you have? (Check all that apply.)</p> <p><input type="checkbox"/> None
<input type="checkbox"/> Field training exercises
<input type="checkbox"/> Combat duty
<input type="checkbox"/> Humanitarian missions
<input type="checkbox"/> Other (Specify): _____</p> <p>11. On average, how many outpatient visits does your department have per month?</p> <p>_____</p> <p>12. What proportion of your patients are enlisted women?</p> <p><input type="checkbox"/> All or nearly all (81-100%)
<input type="checkbox"/> Most (61-80%)
<input type="checkbox"/> About half (41-60%)
<input type="checkbox"/> Some (21-40%)
<input type="checkbox"/> Few (1-20%)
<input type="checkbox"/> None (0%)</p> <p>13. What is the primary function of your base/post? (Check all that apply.)</p> <p><input type="checkbox"/> Deployment
<input type="checkbox"/> Field training
<input type="checkbox"/> Basic training
<input type="checkbox"/> Technical training
<input type="checkbox"/> Other (Specify): _____</p> <p>14. What other departments provide routine gynecologic care to enlisted Army/Navy women?</p> <p><input type="checkbox"/> Family Practice
<input type="checkbox"/> Internal Medicine
<input type="checkbox"/> Obstetrics/Gynecology
<input type="checkbox"/> Preventive Medicine
<input type="checkbox"/> Active Duty Medical Clinic
<input type="checkbox"/> Other (Specify): _____</p> |
|---|--|

Needs Assessment Survey: Health Education of Enlisted Army and Navy Women

II. Reproductive Health of Enlisted Women—Please answer the following questions on the basis of your clinical experience with enlisted female patients in the Army or Navy.

15. Check one only:
In your experience, what **reproductive health problem** among enlisted women is. . .

	STD infection	Unintended pregnancy	Spontaneous Abortion	Ectopic pregnancy	Yeast infection	Urinary tract infection	Other (Specify)
most common overall?							
most common in the field environment?							
most serious overall?							
most serious in the field environment?							

16. Check one only: In your experience, what is the **most common reason** that enlisted women. . .

	Lack of knowledge	Lack of skills	Negative attitudes about preventive behaviors	Negative Partner's attitudes	Lack of perceived risk	Low self-confidence	Other (Specify)
do not practice safer sex?							
have unintentional pregnancies?							
get non-STD vaginal infections (yeast, etc.)?							

III. Health Services—The following questions ask about the types of health services your department offers to all enlisted female patients during routine health care appointments (annual Pap tests) and during predeployment planning.

17. What does your department do routinely for enlisted female patients **during annual exams**? (Check all that apply.)

- ☐ Contraceptive education and counseling
- ☐ Sexual history taking
- ☐ STD prevention education
- ☐ Education on hygiene practices
- ☐ HIV testing
- ☐ None of the above

Needs Assessment Survey: Health Education of Enlisted Army and Navy Women

18. Check all that apply:
Which of the following are obstacles to providing routine. . .

	Lack of time	Lack of staff	Lack of skilled staff	Not all patients need	Lack of comfort	Not effective	No policy making this standard care	Other (Specify)
contraceptive education/counseling?								
sexual history taking?								
STD prevention education?								
personal hygiene information?								

19. What proportion of your enlisted female patients come to your department for a predeployment medical appointment?

- ☐ All or nearly all (81-100%)
☐ Most (61-80%)
☐ About half (41-60%)
☐ Some (21-40%)
☐ Few (1-20%)
☐ None (0%)
☐ Unknown

20. During predeployment planning, what does your department do routinely to help prepare enlisted female patients for their deployment reproductive health needs? (Check all that apply.)

- ☐ Pregnancy testing
☐ Contraceptive education and counseling
☐ STD prevention education
☐ Prescription medication review
☐ Recommend supplies for period
☐ Education on hygiene practices
☐ No special preparation for deployment
☐ Unknown

21. Check all that apply:
At predeployment, which of the following are obstacles to providing. . .

	Lack of time	Lack of staff	Lack of skilled staff	Not needed by all patients	Lack of comfort	Not effective	No policy making this standard care	Other (Specify)
contraceptive education/counseling?								
sexual history taking?								
STD prevention education?								
personal hygiene information?								

22. During predeployment planning, what medical and hygiene supplies does your department recommend be supplied to units for the reproductive health needs of enlisted women? (Check all that apply, and add others not listed.)

- ☐ Not responsible for medical supplies.
☐ Oral contraceptives
☐ Unscented tampons
☐ Unscented panty liners
☐ Unscented wet-wipes
☐ Yeast infection medication
☐ Female urinary director
☐ Other: _____

☐ Unknown

Needs Assessment Survey: Health Education of Enlisted Army and Navy Women

IV. Health Education—We are interested in how you feel about the health care and the health education that enlisted women receive in the military.

23. Check all media that apply: On which of the following health topics has your department provided education to enlisted women in the past year?

	Course or presentation	Written materials	Video or audiotaped instruction	Computer-based instruction	None
Birth control/family planning					
STD prevention education					
AIDS or HIV infection prevention					
Prevention of vaginal infections					
Personal hygiene					
Empowerment/assertiveness skills					

24. Check one box in each area:

Rate the health education that enlisted women receive in the military.

	Quality			Amount		
	Poor	Average	Good	Too Little	Enough	Too Much
Contraceptive education						
STD prevention education						
Personal hygiene education						
Empowerment/assertiveness skill training						
Other:						

25. Other comments about enlisted women's reproductive health? (Please describe briefly below.)

Appendix H

Expert Panel Meeting Report

CD-ROM Technology to Increase Appropriate Self-Care Behaviors Among Enlisted Army and Navy Women

First Advisory Panel Meeting Notes December 2 & 3, 1996

Introduction

The purpose of the first advisory panel meeting was to develop goals and objectives and to gather information to help in the development of the needs assessment instruments and strategy. The advisory group meeting also served to begin the development of behavioral and educational objectives that will guide the project and development of materials.

The meeting was hosted by the Macro project staff: Dr. Robert Gold, Civilian Principal Investigator; Nancy Meyer, Project Director; and Susan Allison, Research Associate. The advisory panel consisted of health care providers and psychologists with experience serving military populations:

- **Dr. Evelyn Lewis**, Military Principal Investigator and Assistant Professor, Department of Family Practice at the Uniformed Services University of the Health Sciences (USUHS)
- **Dr. Linda Lawrence**, expert in operational military medicine and emergency medicine and Assistant Professor, Department of Military and Emergency Medicine, USUHS
- **Dr. Mary Maryland**, expert in military nursing and cultural diversity and Coordinator of Community Health Programs at the University of Illinois, Chicago College of Nursing
- **Dr. Gloria Richard-Davis**, STD education and gynecological care specialist and Assistant Professor, Department of Obstetrics and Gynecology, Tulane University Medical Center
- **Dr. Tracy Sbrocco**, expert in psychological issues, decision making, and sexual dysfunction and Assistant Professor, Department of Medical and Clinical Psychology, USUHS.

The role of the advisory panel is to provide expertise and insight into developing and delivering a women's health intervention in a military health care setting. During this meeting, the panel helped create an initial vision and broad goals. Throughout the project, the panel will offer their expertise and perspective through the review of objectives and materials and the monitoring of progress toward project goals. The panel will review the three needs assessment surveys and provide input during the multimedia intervention development stage. The panel will also keep Macro staff informed of policy changes that may affect the project and may be asked to provide contacts or other references related to the military health care setting.

Overview of Project

A brief overview of the needs assessment study was given by Nancy Meyer. The following is a synopsis of her presentation.

Explanation of Study Phases:

The first step of the project is the **needs assessment**. Three types of individuals will receive mail surveys in this process: (1) enlisted Army and Navy women, (2) clinicians working with Army and Navy women, and (3) OB/GYN department heads. In addition, focus groups to collect more qualitative information will be conducted with Army and Navy women, and separate focus groups will be held for clinicians. The sampling strategy for the mail surveys has not yet been determined. The focus groups participants will be recruited at one Army and one Navy base.

The next step in the process is the **intervention development stage**. The information gleaned from the needs assessment will be used to structure, plan, and develop the multimedia program. The program will focus on the most pressing and relevant needs that are revealed during the needs assessment. At the completion of this phase, the program will be field tested and revised as needed.

Following completion of the multimedia program, an **efficacy study** will be conducted at two clinics, one that serves Army women and another that serves Navy women. Women coming in for their Pap tests will be invited to participate in the study on a rolling recruitment basis (N=528). There will be a also be a control group of women who receive their usual gynecological care. Those who participate will take a pre-test. The pre-test will be followed by use of the multimedia program. The women who participate will have 3 post-tests: one immediately after using the program, a post-test six months later, and finally another at 1 year following intervention.

Research and Logistical Issues Related to the Project

A number of practical issues related to the study were raised during the advisory panel meeting. Among those discussed are the sensitivity of the questions and obtaining approval from the Human Subjects Committee. Another pertinent issue discussed is the potential problem of tracking and follow-up of the women for post-testing purposes. Due to the transitory nature of enlisted women, several possible solutions were proposed in order to ensure maximum follow-up.

One issue raised related to needs assessment and the important persons to survey. Specifically, the advisory panel questioned only giving the clinicians survey to physicians. Nurse practitioners and physician's assistants often give routine gynecological care and may be appropriate people to receive this survey. The panel also discussed the relative importance of surveying the OB/GYN department heads. Strategies to increase return rates among all those surveyed.

The advisory panel was asked about the appropriateness of asking about the sex of the women's partners. More specifically, the group discussed the necessity of knowing whether the women's partners are male or female and the prudence of asking this question in view of the military's view on same-sex partners and the "don't ask, don't tell" policy.

The strict requirements of the Human Subjects Committees and the IRB Boards were considered. Nancy Meyer shared with the group some of the difficulties she has encountered dealing with these two committees. For example, the Human Subjects Committee wants Macro to include a consent form with each mailed survey that must be witnessed by someone other than the person completing the survey. Given that consent is implied by the participant when she completes and returns the survey, this requirement seems unnecessary. The panel indicated that any requirements surrounding consent or confidentiality that seem excessive are simply imposed due to the sensitive nature of the questions. Since this survey deals with sexual and reproductive knowledge and behavior, more stringent requirements are being imposed. Macro staff takes these issues very seriously and intends to take every step to protect the rights of the women participating and ensure that their confidentiality is not violated.

The need to ensure that the instruments can be easily read by women of varying levels of literacy and are acceptable and understandable by women of differing backgrounds and cultures was briefly addressed. Therefore, the instruments will be reviewed for readability and pilot tested to ensure that they are culturally sensitive.

Overview of Macro and Demonstration of Multimedia Materials

Dr. Gold gave a verbal overview of Macro and demonstrated some sample multimedia and online applications developed by Macro. He inquired of the panel participants whether they were aware of any similar projects being conducted for or within the Department of Defense. Dr. Gold also gave a brief overview of multimedia terminology and gave examples of some state of the art technology that may be used for this project. This background information served to facilitate discussion of the application that will be developed. The materials shown illustrated different learning modalities including simulation, gaming, review, and practice, and tutorials.

Use of the PRECEDE/PROCEED Planning Framework

In order for the advisory panel to gain a better understanding of the planning framework being used for designing this educational intervention, Dr. Gold gave an overview of the PRECEDE/PROCEED model and emphasized that it is a planning model and not a behavioral model. Dr. Gold briefly discussed each phase of the model and discussed their relative importance to the overall project. The following is a listing of the phases and a brief description of each:

- **Social Diagnosis** - The social diagnosis serves as a community needs assessment and provides the community an opportunity to be active participants in the planning process. It also helps the community develop a sense of ownership in a program.
- **Epidemiological Diagnosis** - This part of the process asks the community to examine their needs in relation to what the data indicate are the most pressing health concerns. It allows the planner to develop some broad goals and objectives for the entire intervention.

- Behavioral and Environmental Diagnosis - During this phase of the planning process, the user explores the behavioral, lifestyle and environmental factors that play a role in the health issues and concerns previously identified in the social diagnosis.
- Educational and Organizational Diagnosis - At this point in the planning process, the predisposing, reinforcing, and enabling factors that impact the elements identified in the behavioral and environmental diagnosis are examined. Numerous causes may surface, but in order to determine where to intervene, attention to factors that are most important and changeable is the direction efforts are best focused.
- Administrative and Policy Diagnosis - This final planning step involves the consideration of those existing influences that present constraints and barriers to overcoming the behavioral and environmental factors previously identified.

The PRECEDE/PROCEED model framework guided much of the remaining meeting and discussion among panel members and Macro staff. Specifically, the meeting focused on the development of health objectives and behavioral objectives, and on identifying predisposing, enabling, and reinforcing factors for each of the pertinent risk behaviors.

Vision Statement

The vision statement is a broad statement that is the dream of what a project will accomplish. As a starting point, the vision statement provides direction and purpose. Each of the advisory panel members drafted a vision statement for the project. As the members of the panel each read their vision statement aloud, key elements were written on a chart until all unique items were listed. Those elements are included in the following comprehensive statement in italics:

- The project will produce an *individualized, context-sensitive* health education program for *enlisted Army and Navy women and their health care providers* that provides *assessment, diagnostic information, and education*. This planned intervention will *target environmental situations and conditions (high risk sexual behaviors and related behaviors, related attitudes, and base knowledge)*, and *facilitate access and utilization of necessary resources for preventive care (education, early intervention, and treatment, and relapse prevention)*. This will result in the *elimination of HIV/STD infection, unplanned pregnancy, vaginal infection, and related conditions*, which will *improve the physical and mental health, military readiness, and quality of life* for enlisted women.

Later, when discussing important behavioral objectives for the project, the advisory panel discussed the need for the target population (enlisted women) to become advocates for their own health and to take responsibility for preparing for self-care needs. The concepts of self-advocacy and self-care were related to all three health issues targeted by the proposed project: STD infection, unplanned pregnancy, and vaginal infections. In addition, these concepts were seen as

crucial because military policies may not be in place to support and reinforce preventive health behavior. Therefore, another vision for the project is *an enlisted female population that is able to advocate for their own health and to take action to prepare for their self-care needs*.

The advisory panel also strongly supported another vision for the project, relating to dissemination of research findings through the research literature. They felt that the study had the potential to provide important information for others working in women's health in the military. A draft vision for this aspect of the project is as follows:

- The project will also *add to the research literature and knowledge base* on the health needs of military women.

Health Diagnosis

After discussion of the three target areas for this project (unplanned pregnancies, STD infections, and vaginal infections), the panel drafted a series of health objectives that they feel the intervention can influence. Starting from a base of the Healthy People 2000 Objectives, the panel decided this project should address the objectives in the table below.

Health Objectives

- Decrease the incidence of pregnancy in the field environment.
- Decrease the incidence of unintentional pregnancy.
- Decrease the incidence of initial cases of STD infection.
- Decrease the incidence of recurrent cases of STD infection.
- Decrease the incidence of episodic cases of vaginal infection (non-STD).
- Decrease the incidence of chronic cases of vaginal infection (non-STD).

Behavioral and Environmental Diagnosis

During the next phase of the meeting, the panel spent time discussing and identifying many of the factors that play a role in unplanned pregnancies, STD infections, and vaginal infections among enlisted women. The table below outlines some of the behavioral and environmental factors that the advisory group identified that are important when this population is making decisions that will affect their reproductive health.

	Behavioral	Environmental
Unplanned Pregnancy	<ul style="list-style-type: none"> • lack of consistent use of contraceptives • improper use of contraceptives • motivation (conscious, unconscious) marriage, avoid deployment, etc. • knowledge of reproductive system • side effects of contraceptives • use of ineffective methods • woman's ability to ask questions of provider • frequency of sexual activity • alcohol and drug use • self esteem/goals/coping resources/locus of control • support systems • religious beliefs/values • partner's support/attitudes • previous pregnancies/abortions • attitudes toward abortion • sexual abuse • seriousness of relationship to partner 	<ul style="list-style-type: none"> • contraceptive policy for deployment and training - long and short term • quality of information from provider • availability of outside sources of care (particularly overseas) • consistency of care • gender of provider • sensitivity of provider • comfort level/rapport with provider • military policy toward contraceptives and abortion • availability of contraceptive that woman is currently using
STD Infection	<ul style="list-style-type: none"> • unprotected intercourse • use of drugs or alcohol • non-adherence with treatment • reporting behavior - to partners and clinicians • obtaining barrier methods • risk-taking behaviors • multiple sex partners • oral contraceptive use • improper use of barrier methods • re-infection 	<ul style="list-style-type: none"> • field duty (field packs) • policy of field packs • accessibility of condoms • deployment • reassignment • shore leave • lack of screening • providers ability to ask about sexual practices • hierarchy of command • provider experience

Vaginal Infection	<ul style="list-style-type: none"> • education • knowledge of normal physiology • diet • stress • oral contraceptive use • medication • improper hygiene • douching practices • partner not receiving treatment • lack of self-diagnosis skills • lack of hygienic practices in the field 	<ul style="list-style-type: none"> • lack of ventilation in uniforms • availability of medical services, medications in the field • field duty - no showers, etc. • lack of guidelines for medics in field • quality of care - overall, in the field • need for provider visit for over-the-counter medications (free of charge) • comfort level with provider • authority level of provider in dispensing medications in the field
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Following the drafting of the behavioral and environmental factors that play a role in influencing enlisted women's reproductive health, the panel and Macro staff divided into two working groups to develop behavioral and environmental objectives that would address these factors. One group worked on STDs and the other group discussed unplanned pregnancies. The group worked together to draft objectives for preventing vaginal infections. Each group developed objectives pertaining to enlisted women and objectives for their providers. The table below outlines those objectives that were drafted during these discussions.

Behavioral Objectives		
Health Problem	Enlisted Women	Providers
Unplanned Pregnancies	<p>Increase the number of women who:</p> <ul style="list-style-type: none"> • model positive behavior (communication, negotiation skills) • identify risks for unplanned pregnancies • improve their motivation to eliminate risk-taking behaviors (multiple partners, etc.) • identify barriers to contraceptive use • consistently seek contraceptive counseling • continue to use effective contraception (including in the field, all settings) 	<p>Increase the number of providers who:</p> <ul style="list-style-type: none"> • advise women about proper use of contraceptives • improve accessibility of to a variety of options • routinely assess and counsel regarding contraception • provide for continuing contraceptive needs in the field • screen for pregnancy before deployment • improve women's knowledge of contraceptive options and use
STD Infections	<p>Increase the number of women who:</p> <ul style="list-style-type: none"> • advocate for their own health • prepare for their self-care needs • correctly and consistently use barrier methods • has access to barrier methods in all settings • take sexual risks under the influence of alcohol and drugs • adhere to treatment plans (report problem, understand treatment, follow course of medication) • understand symptoms and risk factors for STDs • engage in serial monogamy (have women understand the risk) • do not become reinfected 	<p>Increase the number of providers who:</p> <ul style="list-style-type: none"> • take sexual histories (may indicate need for screening) • are comfortable discussing STD prevention • are sensitive to cultural issues that may influence sexual behavior • provide written and/or verbal information about STD prevention or treatment
Vaginal Infections	<p>Increase the number of women who:</p> <ul style="list-style-type: none"> • consistently practice proper hygiene • recognize and seek appropriate care for vaginal infection signs and symptoms 	<p>Increase the number of providers who:</p> <ul style="list-style-type: none"> • address reproductive tract health needs in predeployment planning. • properly assess and diagnose vaginal infection in the field.

After drafting a fairly complete list of objectives, the group began to narrow the list to those objectives that would invoke the most change and would best be addressed by a multimedia intervention. During this discussion, the panel was able to identify two or three key objectives in each area. The following table organizes these objectives.

Behavioral Objectives		
Health Problem	Increase by __ percent the proportion of enlisted women who:	Increase by __ percent the proportion of military health care providers who:
Unplanned Pregnancy	<ul style="list-style-type: none"> Consistently seek contraceptive counseling. Correctly and consistently use effective contraception 	<ul style="list-style-type: none"> Routinely and correctly assess and advise enlisted women on contraceptive methods. Routinely assess contraceptive needs in predeployment planning.
STD Infection	<ul style="list-style-type: none"> Correctly and consistently use barrier methods of contraception. Adhere to STD treatment plans when diagnosed with STDs. Reduce high risk behaviors for STDs (multiple partners, unprotected intercourse, and alcohol and drug use) 	<ul style="list-style-type: none"> Routinely provide appropriate screening, assessment and advice on STD prevention and treatment. Address STD prevention and treatment needs in predeployment planning.
Vaginal Infection	<ul style="list-style-type: none"> Consistently practice proper hygiene. Recognize and seek appropriate care for vaginal infection signs and symptoms. 	<ul style="list-style-type: none"> Address reproductive tract health needs in predeployment planning. Properly assess and diagnose vaginal infection in the field.

The group spent some time discussing the appropriate percentage that should fit into the blanks above. After some discussion, most panel members felt as though it would be very difficult to set a certain goal percentage without having adequate baseline data for each of these objectives. In addition, the group was concerned that the success of the project may be misrepresented if initial screening efforts serve to identify an increase in the number of STDs, vaginal infections, and unplanned pregnancies.

Discussion of Educational Strategies

Dr. Gold queried the group as to how they feel the application should be presented. He asked for the group's opinion as to what the military environment would support in terms of delivering this program. He asked about various themes that should be incorporated, how the application should be structured. The group responded by discussing the military's method of training as often involving repetition. The group also discussed appropriate times during the military career of an enlisted woman that the intervention should be delivered. Many in the group felt that in-processing or right at the start of the soldier's career would be an ideal time to expose her to the application. They also spoke of the importance of continued exposure to the intervention messages throughout the military woman's career.

As part of discussing how and when the intervention should be delivered, the panel discussed various themes that would be appealing to enlisted military women. It is important that the tone of the application is also attractive to those in the military who would make decisions regarding its use. Most member of the panel think that the use of an action-oriented, readiness training focus would serve to appeal to both the women and their commanders. They referred to the attractive Army recruitment ads ("Be all that you can be.") that emphasize the exciting parts of military services.

The group also discussed some more practical points related to delivery of the multimedia intervention. Specifically, they were concerned about the location of the computer that the women would use and maintaining privacy while responding to assessments dealing with sexual risk taking. The group suggested to Macro that we inquire of the clinics their ability to house a computer in a private location for use in the study and to ask the medical officers on each base what they feel they can realistically implement. The group also suggested to Macro that we include as part of the needs assessment the task of finding out what other health education activities are taking place on base and who is responsible for them.

Dr. Gold also asked the group to discuss other effective health education interventions conducted within the military. The group used the example of the educational efforts of the military surrounding the effects of nerve gas and how to protect oneself against nerve gas attacks. They also discussed the difference between health interventions that are required (immunizations) and those that are deemed to be less important. The panel felt that in order to be acceptable to the higher levels of military command, the application would need to carry the tone of being a tool to affect readiness. As most members of the panel are health care providers, they pointed out the fact that most health care providers in a military setting will view this application as useful, necessary, and very valuable. Therefore, they point out, buy in from this population will not be difficult. However, in order to gain a wide use of the product, it will be necessary to "sell" it to military commanders and those who create military policy. Emphasizing to this population that the application is a tool to be used to maximize readiness and reduce health care costs will be key to gaining their support.

Review of Needs Assessment Instruments

The remainder of the meeting time was used to gain feedback from the panel regarding the needs assessment questionnaires. Prior to convening the panel meeting, Macro staff work with Dr. Lewis, the military PI, to identify some of the major areas of study for the needs assessment. Following that meeting, needs assessment instruments were drafted and subsequently given to the panel participants at the end of Day 1 of the meeting to be reviewed and discussed the following day.

Discussion of the draft instruments proved to be very useful. Macro staff worked with panel to determine the best wording of the questions and to ensure that the answer choices supplied for each item were the appropriate ones. The group discussed two instruments: the instrument to be used with the enlisted women and that to be used with health care providers.

Among those specific items discussed on the women's instrument were those questions pertaining to demographics, date of separation, and use of the terms rank or grade. In addition, the wording of the knowledge questions and the choice provided for them were discussed at length. Some specific issues surrounding the knowledge questions dealt with the use of terms that the target population would understand, the importance of making sure the questions are not misleading in their tone, and keeping the instrument to reasonable length.

Following discussion of the women's instrument, the group discussed the instrument to be used with the health care providers. A few of the panel members brought up the importance of knowing whether the providers received readiness training during their residencies or other training. Another point mentioned is that it will be important to know the respondents level of medical expertise (physician, nurse practitioner, physician's assistant, medic, etc.).

A portion of the health care provider's instrument will address the provider's attitudes and practices about what is included in pre-deployment planning and care in the field environment related to reproductive health. The panel suggested there be some question that addresses whether providers treated all populations similarity. For example, the question of whether standard care for single women differs from standard care for married women. Also, the panel felt that some item addressing sexual history taking and providers comfort level with taking sexual histories, as well as their usual practices surrounding it should be included.

Appendix I

Single Project Assurance



DEPARTMENT OF THE ARMY
OFFICE OF THE SURGEON GENERAL
5109 LEESBURG PIKE
FALLS CHURCH, VA 22041-3258



REPLY TO
ATTENTION OF

September 10, 1996

Office of the Deputy Chief of Staff
for Regulatory Compliance and Quality
Human Use Review and
Regulatory Affairs Division

SUBJECT: Protocol Entitled "CD-ROM Technologies to
Increase Appropriate Self-Care and Preventive Behaviors
Among Army and Navy Women," Submitted by Robert S. Gold,
Ph.D., Dr., P.H., Macro International, Inc., Proposal Log
No. DE950293 (HURRAD Log No. A-7406)

Robert S. Gold, Ph.D., Dr., P.H.
Macro International, Inc.
11785 Beltsville Drive
Calverton, Maryland 20705

Dear Doctor Gold:

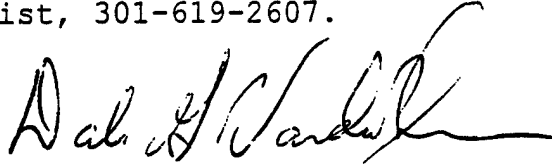
Review of the information provided for a Single
Project Assurance for the protocol entitled "CD-ROM
Technologies to Increase Appropriate Self-Care and
Preventive Behaviors Among Army and Navy Women" has been
completed.

Based upon that review, DOD Single Project Assurance
Number **S-20027** is assigned to Macro International. Please
note that this number expires five years from the date of
issue or upon expiration of the grant, whichever comes
first, and must be renegotiated with the Human Use Review
and Regulatory Affairs Division, U.S. Army Medical Research
and Materiel Command.

Changes in the ethics review board membership or
policies should be reported when they occur.

Documentation of annual review and approval must be provided to this office no later than August 16, 1997, and annually thereafter until expiration of the project.

Point of contact for all questions is Ms. Cathy Smith, Human Use Review Specialist, 301-619-2607.

A handwritten signature in black ink, appearing to read "Dale G. Vander Hamm", with a stylized flourish at the end.

Dale G. Vander Hamm
Major, Medical Service Corp
Chief, Human Use Review and
Regulatory Affairs Division

Enclosure

Copies Furnished:
USAMRMC, ATTN: MCMR-PLF (Dr. Modrow)

Macro International Inc.

Assurance of Compliance with Department of Defense Regulations for Protection of Human Research Subjects

Macro International Inc. hereinafter known as the "institution", hereby gives assurance that it will comply with the Department of Defense (DOD) regulations for the Protection of Human Research Subjects (DOD Regulations 32 CFR 219, Part 1 and, where applicable, HHS Regulation 45 CFR 46, Subparts B, C, and D), and Title 10, United States Code, Section 980 (hereinafter referred to as 10 USC 980) as specified below.

PART 1

Ethical Principles and Institutional Policies Governing Research Involving Human Subjects

1. Applicability

Except for research exempted or waived under the Department of Defense regulations 32 CFR 219.101, and 10 USC 980, Part 1 of this Assurance applies to all research involving human subjects, and all other activities which even in part involve such research regardless of whether the research is otherwise subject to federal regulation, if:

- A. the research is sponsored by this institution, or
- B. the research is conducted by or under the direction of any employee or agent of this institution in connection with institutional responsibilities, or
- C. the research is conducted by or under the direction of any employee or agent of this institution using an property or facility of this institution, or
- D. the research involves the use of this institution is nonpublic information to identify or contact human research subjects or prospective subjects.

II. Ethical principles Governing Human Subjects Research

This institution is guided by the ethical principles regarding all research involving humans as subjects as set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled, Ethical Principles and Guidelines for the Protection of Human Subjects of Research (the "Belmont Report") and as specified below.

- A. This institution recognizes the principles of respect for persons, beneficence (including minimization of harms and maximization of benefits), and justice as stated in the Belmont Report and will apply these principles in all research covered by this Assurance.

- B. This institution acknowledges and accepts its responsibilities for protecting the rights and welfare of human research subjects.

III. Policies

- A. This institution acknowledges that it and its investigators bear full responsibility for the performance of all research covered by this Assurance, including full responsibility for complying with Federal, state, and local laws as they may relate to such research.
- B. This institution assures that before human subjects are involved in research, proper consideration will be given to:
- (1) the risk to the subjects,
 - (2) the anticipated benefits to the subjects and others,
 - (3) the importance of the knowledge that may reasonably be expected to result,
 - (4) the informed consent process to be employed,
 - (5) the provisions to protect the privacy of subjects, and
 - (6) the additional safeguards for vulnerable populations.
- C. This institution recognizes the need for appropriate additional safeguards in research involving subjects who are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.
- D. This institution encourages and promotes constructive communication among the institutional officials, research administrators, department heads, research investigators, clinical care staff, human subjects, and all relevant parties as a means of maintaining a high level of awareness regarding the safeguarding of the rights and welfare of the subjects.
- E. This institution will exercise appropriate administration overview carried out at least annually to assure that its practices and procedures designed for the protection of the rights and welfare of human subjects are being effectively applied.

PART 2

IRB, Institution, and Investigator Compliance with 32 CFR 219 and 45 CFR 46 and 10 USC 980

I. Applicability

Part 2 of this Assurance applies to the following research project which is conducted or sponsored by this institution and supported by the Department of Defense (DOD).

Project title: CD-ROM Technology to Increase Self-Care and Preventive Health Behaviors Among Enlisted Army and Navy Women

HURRAD Log No : A-7406

Project Investigator or Director: Robert S. Gold, Ph.D., Dr. P.H.

II. Institutional Responsibilities

- A. This institution has complied and will continue to comply with the requirements of 32 CFR 219 Part 1, and 45 CFR 16 Subparts B, C, D, and 10 USC 980, as specified below.
- B. In accordance with the compositional and quorum requirements of 32 CFR 219.107 and 219.108, the Institutional Review Board (IRB) designated in Part 3 and in the attached roster is responsible for the initial and continuing review of this project.
- C. This institute has provided and will continue to provide both meeting space for the IRB and sufficient staff to support the IRB's review and record keeping duties.
- D. In addition to the review and approval of the IRB, this institution has reviewed and sponsors the project referenced above.

III. IRB Review

- A. The IRB shall review and have the authority to approve, require modification in, or disapprove this research or proposed changes in it before human subjects may be involved.
- B. The convened IRB reviewed and approved the above project.

- C. The IRB determined, in accordance with the criteria found at 32 CFR 219.111, and where applicable, 45 CFR 46 Subparts B, C, D, and 10 USC 980, that protection for human research subjects are adequate.
- D. The IRB has the authority to suspend or terminate approval of the above referenced research in accordance with 32 CFR 219.113 for (1) non-compliance with 32 CFR 219, and this Assurance document or the IRB's requirements, and (2) for elimination of unexpected serious harm to subjects.
- E. The IRB has determined that legally effective informed consent **[copy of document must be attached unless specified otherwise by DOD]** will be obtained in a manner and method which meets the requirements of 32 CFR 219.116 and CFR 219.117.
- F. Certification of IRB approval, at least annually shall be submitted to the Department of Defense awards unit that issued the award, as a condition for receipt of funds for a non-competing continuation and/or additional involvement of human subjects.
- G. Continuing review by the IRB shall be conducted at intervals appropriate to the degree of risk, but not less than once per year (32 CFR 219.109[e]). The IRB may be called into an interim review session by the Chairperson at the request of an IRB member or Institutional Official to consider any matter concerned with the rights and welfare of human subjects.
- H. The IRB shall prepare and maintain adequate documentation of its activities in accordance with 32 CFR 219.115.
- I. The IRB shall report promptly to institutional officials and the Department of Defense (DOD):
 - (1) any serious or continuing noncompliance by investigators with the requirements of the IRB,
 - (2) any suspension or termination of IRB approval,
 - (3) any unanticipated problems or injuries involving risks to subjects or others, and
 - (4) any changes in this research activity which are reviewed and approved by IRB.
- J. Where appropriate, the IRB will determine that adequate additional protections are ensured for fetuses, pregnant women, prisoners, and children as required under Subparts B, C, and D of 45 CFR 46 and 10 USC 980. The IRB will notify DOD promptly when IRB membership is modified to satisfy the requirements at 45 CFR 4.304 and when the IRB fulfills its duties under 45 CFR 46.305(c).

- K. The IRB will comply fully with the requirements of all applicable Federal policies and guidelines, including those concerning notification of sero-positivity, counseling, and confidentiality of subjects.
- L. The IRB will comply fully with 10 USC 980 which states: if an individual cannot give his/her own consent, and there is no intent to benefit the subject, (for example, minors) he/she cannot be entered into a study funded by the Department of Defense. This is legally binding and there will be no exceptions.

IV. Research Investigator Reporting Responsibilities

- A. Investigators acknowledge and accept their responsibility for protecting the rights and welfare of human research subjects for complying with all applicable provisions of this Assurance and 32 CFR 219, 45 CFR 46 and 10 USC 980.
- B. Research investigators shall report promptly to the IRB proposed changes in this research activity and the changes shall not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to the subjects. Any change in the investigator or change to the protocol shall be reported to the Human Use Review and Regulatory Affairs Division.
- C. Research investigators shall report promptly to the IRB any unanticipated problems involving risks to subjects and others. Any serious and unexpected adverse event(s) shall be reported to the Human Use Review and Regulatory Affairs Division.

PART 3

Certification of IRB Approval and Institutional Endorsement

Project title: CD-ROM Technology to Increase Self-Care and Preventive Health Behaviors Among Enlisted Army and Navy Women

HURRAD Log No.: A-7406

Project Investigator of Director: Robert S. Gold, Ph.D., Dr. P.H.

Date of IRB Approval: August 16, 1996

Date of Next IRB Review: January 30, 1997

The officials signing below assure that the project referenced above was approved by the IRB on the date indicated and that the project will be conducted in accordance with the requirements of Title 32, Part 219 and Title 45, Part 46 of the Code of Federal Regulations, 10 USC 980, and this Assurance document.

A date roster listing the current membership of the designated IRB is attached:

I. Authorized Official of the Institution Providing This Assurance

Signature James Ross Date: August 16, 1996
11785 Beltsville Drive, Suite 300
Calverton, MD 20705
(301) 572-0200
(301) 572-0999 Fax

II. Authorized Official of the Institution with the IRB
(Include only if different for the Institution above)

This Institution authorizes the designation of its IRB for review of the project referenced in this Assurance.

Signature NA Date: _____
Signature block
Address
Telephone
Fax

III. IRB Chairperson
(Must be completed in all classes (see IRB membership list))

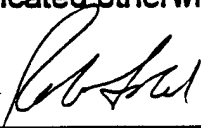
Signature James G. Ross Date: August 16, 1996
James G. Ross
Macro International Inc.
11785 Beltsville Drive, Suite 300
Calverton, MD 20705
301-572-0208
301-572-0986

MPA number if applicable: [N/A]

IV: Responsible Project Investigator or Director at Institution Providing this Assurance

I have attached copies of all DOD requested and IRB approved Informed Consent Documents to be used in this project unless the designated IRB operates under a DOD approved Multiple Project Assurance (MPA) or unless DOD has indicated otherwise.

Signature



Date:

8/29/96

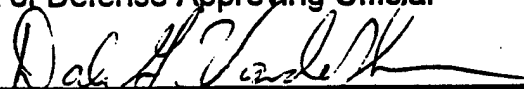
Signature block [Principal Investigator]
11785 Beltsville Drive, Suite 300
Calverton, MD 20705
(301) 572-0335
(301) 572-0999 Fax

- SPACE BELOW FOR DEPARTMENT OF DEFENSE -

All parts of this Assurance are in compliance with the requirements of Title 32, Part 219, Title 45, Part 46 of the Code of Federal Regulations, and 10 USC 980.

Department of Defense Approving Official

Signature



Date:

9 September 1996

Name: MAJ Dale G. Vander Hamm, MS, Chief, HURRAD
Address: Assurance Coordinator, Assurance Branch
Human Use Review and Regulatory Affairs Division (HURRAD)
U.S. Army Medical Research and Materiel Command,
Fort Detrick, Frederick, MD 21702-5012

Telephone #: 301-619-2165/2602
FAX #: 301-619-7803

ASSURANCE NUMBER: S-20027 *

An application for new or competing support for continuation in which human subjects will be involved will require a new and separate Assurance, unless the activity is exempt under section 32 CFR 219.101 (b).

*Effective for 5 years from date of issue or until expiration of the contract/grant, whichever comes first; must be renegotiated with HURRAD.

INSTITUTIONAL REVIEW BOARD (IRB) MEMBERSHIP

NAME OF IRB AGENCY OR COMMAND: Macro International Inc.

Address and Phone No. Chairperson only:

11785 Beltsville Drive, Suite 300

Calverton, MD 20705

301-572-0208

Members' Names				Highest Scientific	
First	MI	Last	Degree	Affiliation Specialty	w/Institution

(1)	James G. Ross, M.S.	Health Education	Yes
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(2)	Rubén S. Cedeño, Ph.D.	Training	Yes
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	Sia Curtis, Ph.D.	Demography	Yes
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	David Cotton, Ph.D.	Psychology	Yes
--	---------------------	------------	-----

	Maria Fernandez, Ph.D.	Health Education	No
--	------------------------	------------------	----

	A. Billy Jones, M.S.W.	Training	Yes
--	------------------------	----------	-----

	Richard E. Mantovani, Ph.D.	Sociology	Yes
--	-----------------------------	-----------	-----

	A. Elisabeth Sommerfelt, M.D.	Public Health	Yes
--	-------------------------------	---------------	-----

	Eugene Yee, J.D.	Finance	Yes
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(3)

(4)

(1) Denotes Chairperson
(2) Denotes IRB members

(3) Denotes IRB alternates
(4) Denotes non-voting IRB attendee
(expert or technical expertise)

Appendix J

**IRB Project Information Forms, IRB
Approval Letter, & Optional Form 310
(for each instrument)**

IRB PROJECT INFORMATION FORM

Macro International Inc. complies with the Department of Health and Human Services regulations for the protection of human research subjects (45 CFR 46). As part of this compliance, an Institutional Review Board (IRB) has been established to review all research involving human subjects. The IRB is required to review any research project brought before it, or proposed changes to an existing project, before human subjects may be involved. As part of its activities, the IRB is required to submit documentation of its reviews and approvals to the Federal government.

To help the IRB determine if a research project should be reviewed and approved, Macro's project directors are asked to complete the following information. Please submit this form to Jim Ross, IRB chairman (Calverton office, 7th floor). Should you have any questions regarding this form or the IRB review process, please call Jim Ross at ext. 208.

Project Name: CD-ROM Technology to Increase Appropriate Self-Care and
Preventive Behaviors Among Army and Navy Women

Macro Project No.: 1119-01

Funding Agency: Department of Defense

Period of Performance: October 1996 to September 2000

Project Director: Nancy Atkinson Meyer

1. What are the objectives of the study (or of the part involving human subjects)?

The purpose of the study is to investigate enlisted women's needs for basic gynecological and reproductive health education, as evidenced by a needs assessment process to be conducted with military health care providers and enlisted women themselves. Based on the results of the needs assessment, a culturally sensitive, multimedia CD-ROM and accompanying materials will be tested in an Army and Navy medical clinic in conjunction with annual Pap screenings. The technical objectives are as follows:

- 1) To assess the most pressing reproductive and gynecological self-care education needs of enlisted women on base and in the field;
- 2) To assess the range of current health education efforts for enlisted women;
- 3) To enhance enlisted women's self-care and care-seeking knowledge and practices through development and implementation of a culturally sensitive, multimedia educational intervention and accompanying field pocket guide at a medical clinic.

The study involves 4 data gathering activities that involve human subjects:

- 1) Needs assessment mail surveys conducted with nationally representative samples of enlisted women in the Army and Navy (N=500), military health care providers (n=260), and chairpersons of military base OB/GYN services (N=160);
- 2) Needs assessment focus groups with enlisted women in the Army and Navy (N=40) and military health care providers (N=20);
- 3) Alpha Test of prototype intervention with 10 enlisted women at the Uniformed Services University of the Health Sciences (USUHS); and
- 4) Efficacy Study in which 528 enlisted women (264 from the Army and 264 from the Navy) complete a knowledge, attitudes, and practices (KAP survey) before the intervention, immediately after the intervention, at 6 month followup, and at 12 month followup.

This review concerns the first of the data gathering activities; therefore the rest of this IRB form concerns only the needs assessment surveys listed in the first item above.

2. Does the research involve any the following as study subjects? No.

- ☐ Fetuses
- ☐ Children
- ☐ Pregnant women
- ☐ HIV/AIDS-affected persons
- ☐ Mentally disabled persons
- ☐ Prisoners
- ☐ Economically disadvantaged persons
- ☐ Educationally disadvantaged persons

3. How many human subjects will be involved and what are their characteristics?

All of the following groups will be volunteers for the study. They will be recruited via mail surveys sent to a nationally representative sample of each group.

A. Needs Assessment Survey with Enlisted Army and Navy Women

500 Enlisted women in the Navy and the Army residing at military bases in the United States. A two-stage cluster sample will be used to sample enlisted women who will be sent the needs assessment survey. A sample of 4 clusters (military bases), with a subsample of 125 individuals taken in each cluster, will be drawn. These women will mailed a survey with an invitation to participate (Appendix A has the invitation letter, postcard text, and slip sheet text) as well as a Volunteer Agreement Affidavit (Appendix B), and postage-paid return envelope. If no response is received, a second survey will be mailed. If there is still no response, a third survey will be sent via certified mail.

B. Needs Assessment Survey with Military Health Care Providers

260 military health care providers providing OB/GYN services to enlisted women at U.S. military bases. The sample will be based upon approximately 1,000 OB/GYN providers across the 250 military bases in the U.S., for a sub-sample of 4 providers per base at 65 bases (N=260). Like the enlisted women, the clinicians will be mailed a survey with an invitation letter (Appendix C), Volunteer Agreement Affidavit (Appendix D), postage-paid return envelope. If no response is received, a second survey will be mailed. If there is still no response, a third survey will be sent via certified mail.

C. Needs Assessment Survey with Chairpersons of Health Services Serving Enlisted Women's Reproductive Needs

160 Chairpersons of U.S. military medical departments serving enlisted women. A representative sample of 160 military bases will be drawn from 250 military bases around the country. The 4-page survey will be mailed directly to the chairperson of OB/GYN, the troop medical clinic (TMC), or family practice at the medical center of each base, depending upon which department is primarily responsible for the reproductive health care of enlisted women. These individuals will be mailed a survey with an invitation letter (Appendix E), Volunteer Agreement Affidavit (Appendix F), and postage-paid return envelope. If no response is received, a second survey will be mailed. If there is still no response, a third survey will be sent via certified mail.

4. What procedures will human subjects undergo?

A. Needs Assessment Survey: Enlisted Women

Enlisted women will be sent a knowledge, attitudes, and practices (KAP) survey for enlisted women regarding current knowledge levels, self-care and preventive behaviors and attitudes, and use of and attitudes toward medical care services. The surveys will be mailed to each participant with an invitation letter (consent form) and postage-paid return envelope. If no response is received, a second survey will be mailed. If there is still no response, a third survey will be sent via certified mail.

B. Needs Assessment Survey: Military Health Care Providers

Military health care providers will be sent a survey to assess current knowledge, attitudes, and practices regarding the reproductive health of enlisted Army and Navy women. The surveys will be mailed to each participant with an invitation letter and postage-paid return envelope. If no response is received, a second survey will be mailed. If there is still no response, a third survey will be sent via certified mail.

C. Needs Assessment Survey: Department Chairpersons

The survey of military base chairpersons will ask about current medical care practices and health education efforts specifically targeted to enlisted women. The survey will be mailed

directly to the chairperson of departments serving the reproductive needs of enlisted women (OB/GYN, family practice, Troop Medical Clinic) at the medical services at each base. Two follow-up surveys will be sent to non-respondents, the second by certified mail. All surveys will have postage-paid return envelopes included in the package.

5. What are the potential risks to human subjects?

No known risks.

6. What are the potential benefits to human subjects?

Enlisted women participating in the needs assessment survey may have an increased awareness about their health and their health care needs. They will also experience an indirect benefit of improved women's health programming should the study results facilitate the development of an effective intervention.

The information gleaned from military health care providers and OB/GYN service chairpersons may indirectly benefit them. By being able to express their opinions about health care and health service needs of military women, they will be able to influence change in their service delivery capabilities, which is important to them in the environment of military downsizing.

7. How and in what way are human subjects being informed of both the risks and benefits prior to their participation in the study?

The risks are negligible, but the initial letter of invitation and a Volunteer Agreement Affidavit will be used to describe the study and inform all survey respondents of the benefits and risks of participation (Appendices A, C, and E for the invitation letters, and Appendices B, D, and F for the Volunteer Agreement Affidavits). In addition, the covers of the women's survey and the health care provider survey will restate consent issues. The forms will state that participation is voluntary, and refusal will not affect their medical care or military record, and the survey results will be anonymous. The invitation letter will also state that results will be presented in aggregate form.

8. How is the informed consent of human subjects being documented?

DOD requires that informed consent is necessary for participation. Therefore, the "Volunteer Agreement Affidavit" (DA form 5303-R) will accompany a cover letter outlining benefits and risks with each survey form. This will provide a place for survey participants to sign for their consent and return with the survey. They will be told to keep a copy of this form for their records.

9. What is the estimated potential seriousness of risks to human subjects?
CHECK ALL THAT APPLY.

☒ Negligible: virtually none or temporary effect lasting a few hours
☐ Low: temporary effect lasting no more than a few days
☐ Medium: impairment requiring medical or professional attention
☐ High: possible death or permanent injury

10. If you indicated that medium to high risks were possible, what percentage of the population do you estimate is likely to experience such risks?

Not applicable.

11. What steps are being taken to protect human subjects from any known risks during the study?

An invitation letter will outline the risks and benefits of the survey and will inform the respondents of the voluntary nature of participating. The survey data will be encoded with a unique numerical identifier, not personal identifiers. The personal information will be destroyed as soon as the respondent's survey has been received. Participation will be anonymous and confidential in that the data will be reported in aggregate form, and only the study investigators will have access to the data. The name and address of the IRB chairperson is provided on the consent form so that the participant can report any research-related problems. For the lottery, the women who choose to enroll will be asked to send in a postcard separately from their survey, and the postcard will not include the personal identifier.

Regulations from the Army state that we must include a statement in the Volunteer Agreement Affidavits that reads: "Complete confidentiality cannot be promised, particularly to subjects who are military personnel, because information bearing on your health may be required to be reported to appropriate medical or command authorities." We will notify subjects that the information linking their survey to their address will be destroyed upon receipt of the completed survey. Only the investigators will have access to the Volunteer Agreement Affidavits; they will not be forwarded to the U.S. Army because the risks of the study are minimal.

To reduce the likelihood that individual women would be identified from demographic data collected on the enlisted women's survey, three changes were made to the questionnaire. The grade categories were collapsed (see item number 4) so that the woman's exact grade will not be known. Also, the date of entry item (see item number 5) was changed so that only month and year (no day) information will be collected. The question about estimated time of separation (item 6), or ETS, was changed to ask how long the woman planned to be in the service. This last change was recommended because ETS does not reflect planned length of service very well and may only help identify a woman.

In addition to changes in the demographic questionnaires, another step will be taken after data collection is complete to safeguard the identity of individual women. A statistician will review the data set to determine whether an individual woman could be identified in cross tabulations of the demographics. If concerns exist after this review, categories would be further collapsed to reduce the possibility of identification.

12. Does the study involve sufficient risk to subjects to suggest a possible need for monitoring adverse or unexpected effects after the study period? If so, what is planned?

No aspect of the study suggests adverse effects after the study period.

13. Does the research involve any of the following activities: Yes

☒ Obtaining informed consent of study subjects
☐ Notification of sero-positivity
☐ Counseling or therapy
☒ Protection of confidentiality of subjects

14. Does the study design include any of the following? Yes

☒ Survey of individuals (mail or telephone)
☐ Interviews with individuals (in-person or telephone)
☐ Focus groups
☐ Exposure of subjects to a treatment or intervention
☐ Other uses of human subjects (SPECIFY)

15. Is there a basis for claiming an exemption from human subjects clearance? Are you claiming an exemption?

For the surveys, we believe we should be exempted from human subjects clearance because the project:

- 1) will be conducted in established or commonly accepted settings, involving commonly accepted practices as given in 46.101(b)(1);
- 2) involves (a) only the use of educational tests, survey, interview and/or observation procedures; and (b) the collection or study of existing data, documents, records that are publicly available, as given in 46.101(b)(2);
- 3) data will be coded and separated from any consent information, and subjects' names or identifying information will not appear with the data.

16. Does a data collection instrument exist now? (Please attach)

Yes. See Appendices G, H, and I.

17. Do your publication plans in any way potentially compromise the confidentiality or anonymity of subjects?

No. Data will be reported so that anonymity of subjects is protected. Data will be reported in aggregate form with no identifying information connected to it.

18. If the study involves medium to high risk to human subjects, what considerations have you given to alternative designs? Why is this design essential to the study?

Not applicable.

IF THE STUDY INVOLVES MORE THAN SURVEY RESEARCH OR ANY OF THE PROTECTED GROUPS (SEE QUESTION #2), A WRITTEN INFORMED CONSENT FORM MUST BE ATTACHED TO THIS FORM.

Signature: Nancy Atkinson Mayhew

Date: 7/21/97

Return this form to Jim Ross (Calverton Office, 7th floor).

August 29, 1997 (Needs Assessment Survey Among Enlisted Women)

Catherine A. Smith
Human Use Specialist
Human Use and Regulatory Affairs Office
U.S. Army Medical Research and Materiel Command
Building 504xx
Fort Detrick
Frederick, MD 21702-5012

Subject: DAMD 17-96-D-6091 entitled "CD-ROM Technology to Increase Appropriate Self-Care and Preventive Behaviors Among Army and Navy Women";
Component addressed in this letter: Needs Assessment Survey among Enlisted Women

Dear Ms. Smith:

The Institutional Review Board (IRB) of Macro International Inc. was asked to perform a review of the needs assessment survey protocol for the study "CD-ROM Technology to Increase Appropriate Self-Care and Preventive Behaviors Among Army and Navy Women," which is part of the Defense Women's Health Initiative. It was understood that this needs assessment component of the study is an effort to investigate the knowledge, attitudes, and practices of enlisted Army and Navy women concerning gynecological and reproductive health, from the perspective of enlisted women, military health care providers, and chiefs of service (chairpersons of departments supervising reproductive health care of enlisted women). This letter addresses the component which relates to the survey among enlisted women.

Macro operates a 9-person IRB that complies fully with all requirements of the Public Health Service and of the National Institutes of Health. The IRB membership represents such disciplines as medicine, psychology, health education, public health, biology, and sociology.

The project was reviewed by the IRB on July 11, 1997. All IRB members had copies of the questionnaire and of the communications that will be sent to the enlisted women who are asked to participate in the survey. During the meeting, IRB members asked about the compatibility of military regulations with efforts to ensure confidentiality. Suggestions were offered by the IRB to provide assurance of respondent confidentiality. In addition to the materials discussed at the IRB meeting, IRB members have subsequently been informed by study investigators of some modifications in the survey protocol, including modifications which addressed issues raised at the IRB meeting.

The IRB unanimously agreed that, as a survey research project, the needs assessment survey among enlisted women poses minimal to no risk for participating subjects. Suitably, this survey also provides no direct, immediate benefit to subjects, aside from any values that participants may derive from assisting in an enterprise of this importance. Participating institutions stand to benefit from receipt of copies of the published results when the project has been completed. The IRB understands that participating enlisted women will sign an informed consent form (a volunteer affidavit which is consistent with the minimal to no risk nature of this survey); and that principal investigators will retain the completed volunteer agreement

Aug 29, 1997. (Enlisted Women Needs Assessment Survey of the Study "CD-ROM Technology to Increase Appropriate Self-Care and Preventive Behaviors among Army and Navy Women").

Catherine A. Smith
Page 2
August 5, 1997

affidavits.

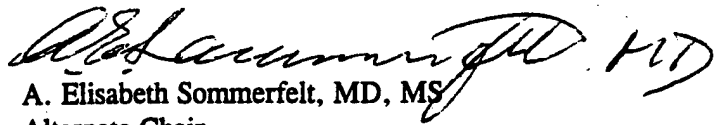
Moreover, it was noted that data will be reported only in the aggregate, and that no installations or subjects will be identified. It is further understood that the investigators will work to ensure that the data file(s) for analysis will not contain information which would permit the identification of individual respondents.

Given that the project poses minimal to no risk for participating subjects, the IRB did not identify any significant areas, beyond those included in the current protocol, in which human subjects require protection. It was noted that, in order to remind subjects who do not initially return a completed survey, their names and addresses will temporarily be retained. However, it was also noted that name and address information will be destroyed as soon as a completed survey questionnaire is received.

We will gladly consult with the IRBs (or the equivalent board / committee) of the participating installations regarding anything related to this needs assessment survey among enlisted women (e.g. we are available if the IRBs of the participating installations conduct a review of the survey protocol). We may be reached at 301-572-0208 (Ross) and 301-572-0875 (Sommerfelt).

Sincerely,

James G. Ross
Chair
Institutional Review Board (IRB)


A. Elisabeth Sommerfelt, MD, MS
Alternate Chair
Institutional Review Board (IRB)

August 29, 1997 (Needs Assessment Survey Among Military Clinicians)

Catherine A. Smith
Human Use Specialist
Human Use and Regulatory Affairs Office
U.S. Army Medical Research and Materiel Command
Building 504xx
Fort Detrick
Frederick, MD 21702-5012

Subject: DAMD 17-96-D-6091 entitled "CD-ROM Technology to Increase Appropriate Self-Care and Preventive Behaviors Among Army and Navy Women";
Component addressed in this letter: Needs Assessment Survey among Military Clinicians

Dear Ms. Smith:

The Institutional Review Board (IRB) of Macro International Inc. was asked to perform a review of the needs assessment survey protocol for the study "CD-ROM Technology to Increase Appropriate Self-Care and Preventive Behaviors Among Army and Navy Women," which is part of the Defense Women's Health Initiative. It was understood that this needs assessment component of the study is an effort to investigate the knowledge, attitudes, and practices of enlisted Army and Navy women concerning gynecological and reproductive health, from the perspective of enlisted women, military health care providers, and chiefs of service (chairpersons of departments supervising reproductive health care of enlisted women). This letter addresses the component which relates to the survey among military clinicians.

Macro operates a 9-person IRB that complies fully with all requirements of the Public Health Service and of the National Institutes of Health. The IRB membership represents such disciplines as medicine, psychology, health education, public health, biology, and sociology.

The project was reviewed by the IRB on July 11, 1997. All IRB members had copies of the questionnaire and of the communications that will be sent to the military clinicians who are asked to participate in the survey. During the meeting, IRB members asked about the compatibility of military regulations with efforts to ensure confidentiality. Suggestions were offered by the IRB to provide assurance of respondent confidentiality. In addition to the materials discussed at the IRB meeting, IRB members have subsequently been informed by study investigators of some modifications in the survey protocol, including modifications which addressed issues raised at the IRB meeting.

The IRB unanimously agreed that, as a survey research project, the needs assessment survey among military clinicians poses minimal to no risk for participating subjects. Suitably, this survey also provides no direct, immediate benefit to subjects, aside from any values that participants may derive from assisting in an enterprise of this importance. Participating institutions stand to benefit from receipt of copies of the published results when the project has been completed. The IRB understands that participating military clinicians are informed of the voluntary nature of the study.

Aug 29, 1997. (Military Clinicians Needs Assessment Survey of the Study "CD-ROM Technology to Increase Appropriate Self-Care and Preventive Behaviors among Army and Navy Women").

Catherine A. Smith
Page 2
August 5, 1997

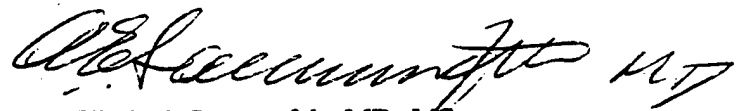
Moreover, it was noted that data will be reported only in the aggregate, and that no installations or subjects will be identified. It is further understood that the investigators will work to ensure that the data file(s) for analysis will not contain information which would permit the identification of individual respondents.

Given that the project poses minimal to no risk for participating subjects, the IRB did not identify any significant areas, beyond those included in the current protocol, in which human subjects require protection. It was noted that, in order to remind subjects who do not initially return a completed survey, their names and addresses will temporarily be retained. However, it was also noted that name and address information will be destroyed as soon as a completed survey questionnaire is received. We agree with the investigators in their claiming an exception from human subjects clearance for this needs assessment survey among military clinicians because: the voluntary nature of the study; the safeguarding of personal information; the survey will be conducted in commonly accepted settings, involving commonly accepted practices, as given in OPRR 46.101(b)(1); it involves the use of survey interview procedures, as given in OPRR 46.101(b)(2) and the collection or study of existing data, documents, records that are publicly available, as given in OPRR 46.101(b)(4).

We will gladly consult with the IRBs (or the equivalent board / committee) of the participating installations regarding anything related to this needs assessment survey among military clinicians (e.g. we are available if the IRBs of the participating installations conduct a review of the survey protocol). We may be reached at 301-572-0208 (Ross) and 301-572-0875 (Sommerfelt).

Sincerely,

James G. Ross
Chair
Institutional Review Board (IRB)


A. Elisabeth Sommerfelt, MD, MS
Alternate Chair
Institutional Review Board (IRB)

August 29, 1997 (Needs Assessment Survey Among Chairpersons)

Catherine A. Smith
Human Use Specialist
Human Use and Regulatory Affairs Office
U.S. Army Medical Research and Materiel Command
Building 504xx
Fort Detrick
Frederick, MD 21702-5012

Subject: DAMD 17-96-D-6091 entitled "CD-ROM Technology to Increase Appropriate Self-Care and Preventive Behaviors Among Army and Navy Women";
Component addressed in this letter: Needs Assessment Survey among Chairpersons

Dear Ms. Smith:

The Institutional Review Board (IRB) of Macro International Inc. was asked to perform a review of the needs assessment survey protocol for the study "CD-ROM Technology to Increase Appropriate Self-Care and Preventive Behaviors Among Army and Navy Women," which is part of the Defense Women's Health Initiative. It was understood that this needs assessment component of the study is an effort to investigate the knowledge, attitudes, and practices of enlisted Army and Navy women concerning gynecological and reproductive health, from the perspective of enlisted women, military health care providers, and chiefs of service (chairpersons of departments supervising reproductive health care of enlisted women). This letter addresses the component which relates to the survey among chairpersons.

Macro operates a 9-person IRB that complies fully with all requirements of the Public Health Service and of the National Institutes of Health. The IRB membership represents such disciplines as medicine, psychology, health education, public health, biology, and sociology.

The project was reviewed by the IRB on July 11, 1997. All IRB members had copies of the questionnaire and of the communications that will be sent to the chairpersons who are asked to participate in the survey.

During the meeting, IRB members asked about the compatibility of military regulations with efforts to ensure confidentiality. Suggestions were offered by the IRB to provide assurance of respondent confidentiality. In addition to the materials discussed at the IRB meeting, IRB members have subsequently been informed by study investigators of some modifications in the survey protocol, including modifications which addressed issues raised at the IRB meeting.

The IRB unanimously agreed that, as a survey research project, the needs assessment survey among the chairpersons poses minimal to no risk for participating subjects. Suitably, this survey also provides no direct, immediate benefit to subjects, aside from any values that participants may derive from assisting in an enterprise of this importance. Participating institutions stand to benefit from receipt of copies of the published results when the project has been completed. The IRB understands that participating chairpersons are informed of the voluntary nature of the study.

Aug 29, 1997. (Chairpersons Needs Assessment Survey of the Study "CD-ROM Technology to Increase Appropriate Self-Care and Preventive Behaviors among Army and Navy Women").

Catherine A. Smith
Page 2
August 5, 1997


Moreover, it was noted that data will be reported only in the aggregate, and that no installations or subjects will be identified. It is further understood that the investigators will work to ensure that the data file(s) for analysis will not contain information which would permit the identification of individual respondents.

Given that the project poses minimal to no risk for participating subjects, the IRB did not identify any significant areas, beyond those included in the current protocol, in which human subjects require protection. It was noted that, in order to remind subjects who do not initially return a completed survey, their names and addresses will temporarily be retained. However, it was also noted that name and address information will be destroyed as soon as a completed survey questionnaire is received. We agree with the investigators in their claiming an exception from human subjects clearance for this needs assessment survey among chairpersons because: the voluntary nature of the study; the safeguarding of personal information; the survey will be conducted in commonly accepted settings, involving commonly accepted practices, as given in OPRR 46.101(b)(1); it involves the use of survey interview procedures, as given in OPRR 46.101(b)(2) and the collection or study of existing data, documents, records that are publicly available, as given in OPRR 46.101(b)(4).

We will gladly consult with the IRBs (or the equivalent board / committee) of the participating installations regarding anything related to this needs assessment survey among chairpersons (e.g. we are available if the IRBs of the participating installations conduct a review of the survey protocol). We may be reached at 301-572-0208 (Ross) and 301-572-0875 (Sommerfelt).

Sincerely,

James G. Ross
Chair
Institutional Review Board (IRB)



A. Elisabeth Sommerfelt, MD, MS
Alternate Chair
Institutional Review Board (IRB)

Protection of Human Subjects
Assurance Identification/Certification/Declaration
(Common Federal Rule)

Policy: Research activities involving human subjects may not be conducted or supported by the Departments and Agencies adopting the Common Rule (56FR120003, June 16, 1991) unless the activities are exempt from or approved in accordance with the common rule. See section 101(b) the common rule for exemptions. Institutions submitting applications or proposals for support must submit certification or appropriate Institutional Review Board (IRB) review and approval to the Department or Agency in accordance with the common rule.

Institutions with an assurance of compliance that covers the research to be conducted on file with the Department, Agency, or the Department of Health and Human Services (HHS) should submit certification of IRB review and approval with each application or proposal unless otherwise advised by the Department or Agency. Institutions which do not have such an assurance must submit an assurance and certification of IRB review and approval within 30 days of a written request from the Department or Agency.

1. Request Type <input checked="" type="checkbox"/> ORIGINAL <input type="checkbox"/> FOLLOWUP <input type="checkbox"/> EXEMPTION		2. Type of Mechanism <input type="checkbox"/> GRANT <input checked="" type="checkbox"/> CONTRACT <input type="checkbox"/> FELLOWSHIP <input type="checkbox"/> COOPERATIVE AGREEMENT <input type="checkbox"/> OTHER: _____	3. Name of Federal Department or Agency and, if known, Application or Proposal Identification No. Department of Defense (DAMD 17-96-C-6091)
4. Title of Application or Activity CD-ROM Technology to Increase Self-Care and Preventive Behaviors Among Army and Navy Women: Needs Assessment Survey for Military			5. Name of Principal Investigator, Program Director, Fellow, or Other Robert S. Gold, Dr.P.H., Ph.D.
6. Assurance Status of this Project (Respond to one of the following) Clinicians <input type="checkbox"/> This Assurance, on file with Department of Health and Human Services, covers this activity. Assurance Identification no. _____ IRB Identification no. _____ <input checked="" type="checkbox"/> This Assurance, on file with (agency/dept) <u>Human Use Review and Regulatory Affairs Division/Dept. of the Army</u> covers this activity. Assurance Identification no. <u>S-20027</u> IRB Identification no. _____ (if applicable) <input type="checkbox"/> No assurance has been filed for this project. This institution declares that it will provide an Assurance and Certification of IRB review and approval upon request. <input checked="" type="checkbox"/> Exemption Status: Human subjects are involved, but this activity qualifies for exemption under Section 101(b), paragraph (b)(1)&(b)(2)			
7. Certification of IRB Review (Respond to one of the following IF you have an Assurance on file) <input checked="" type="checkbox"/> This activity has been reviewed and approved by the IRB in accordance with the common rule and any other governing regulations or subparts on (date) <u>7/11/97</u> by: <input checked="" type="checkbox"/> Full IRB Review or <input type="checkbox"/> Expedited Review <input type="checkbox"/> This activity contains multiple projects, some of which have not been reviewed. The IRB has granted approval condition that all projects covered by the common rule will be reviewed and approved before they are initiated and that appropriate further certification will be submitted.			
8. Comments			

9. The official signing below certifies that the information provided above is correct and that, as required, future reviews will be performed and certification will be provided.		10. Name and Address of Institution Macro International Inc. 11785 Beltsville Drive Calverton, MD 20705
11. Phone No. (with area code) (301) 572-0208	12. Fax No. (with area code) (301) 572-0986	
13. Name of Official James G. Ross		14. Title Vice President and IRB Chair
15. Signature 		16. Date 8/6/97
Authorized for local Reproduction		OPTIONAL FORM 310 (Rev. 1-95) Sponsored by HHS/PHS/NIH

Protection of Human Subjects
Assurance Identification/Certification/Declaration
(Common Federal Rule)

Policy: Research activities involving human subjects may not be conducted or supported by the Departments and Agencies adopting the Common Rule (58FR120003, June 18, 1993) unless the activities are exempt from or approved in accordance with the common rule. See section 101(b) the common rule for exemptions. Institutions submitting applications or proposals for support must submit certification or appropriate Institutional Review Board (IRB) review and approval to the Department or Agency in accordance with the common rule.

Institutions with an assurance of compliance that covers the research to be conducted on file with the Department, Agency, or the Department of Health and Human Services (HHS) should submit certification of IRB review and approval with each application or proposal unless otherwise advised by the Department or Agency. Institutions which do not have such an assurance must submit an assurance and certification of IRB review and approval within 30 days of a written request from the Department or Agency.

1. Request Type <input checked="" type="checkbox"/> ORIGINAL <input type="checkbox"/> FOLLOWUP <input type="checkbox"/> EXEMPTION	2. Type of Mechanism <input type="checkbox"/> GRANT <input checked="" type="checkbox"/> CONTRACT <input type="checkbox"/> FELLOWSHIP <input type="checkbox"/> COOPERATIVE AGREEMENT <input type="checkbox"/> OTHER: _____	3. Name of Federal Department or Agency and, if known, Application or Proposal Identification No. Department of Defense (DAMD 17-96-C-6091)
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4. Title of Application or Activity CD-ROM Technology to Increase Self-Care and Preventive Behaviors Among Army and Navy Women: Needs Assessment Survey for Military

5. Name of Principal Investigator, Program Director, Fellow, or Other
Robert S. Gold, Dr.P.H., Ph.D.

6. Assurance Status of this Project (Respond to one of the following) Clinicians

- ☐ This Assurance, on file with Department of Health and Human Services, covers this activity:
Assurance Identification no. _____ IRB Identification no. _____
- ☒ This Assurance, on file with (agency/dept) Human Use Review and Regulatory Affairs Division/Dept. of the Army covers this activity:
Assurance Identification no. S-20027 IRB Identification no. _____ (if applicable)
- ☐ No assurance has been filed for this project. This institution declares that it will provide an Assurance and Certification of IRB review and approval upon request.

☒ Exemption Status: Human subjects are involved, but this activity qualifies for exemption under Section 101(b), paragraph (b)(1)&(b)(2)

7. Certification of IRB Review (Respond to one of the following IF you have an Assurance on file)

- ☒ This activity has been reviewed and approved by the IRB in accordance with the common rule and any other governing regulations or subparts on (date) 7/11/97 by: ☒ Full IRB Review or ☐ Expedited Review
- ☐ This activity contains multiple projects, some of which have not been reviewed. The IRB has granted approval condition that all projects covered by the common rule will be reviewed and approved before they are initiated and that appropriate further certification will be submitted.

8. Comments

9. The official signing below certifies that the information provided above is correct and that, as required, future reviews will be performed and certification will be provided.

11. Phone No. (with area code)
(301) 572-0208

12. Fax No. (with area code)
(301) 572-0986

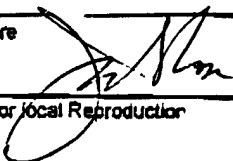
10. Name and Address of Institution

Macro International Inc.
11785 Beltsville Drive
Calverton, MD 20705

13. Name of Official
James G. Ross

14. Title
Vice President and IRB Chair

15. Signature



16. Date
8/6/97

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OPTIONAL FORM 310 (Rev. 1-95)
Sponsored by HHS/PHS/NIH

Protection of Human Subjects

Assurance Identification/Certification/Declaration

(Common Federal Rule)

Policy: Research activities involving human subjects may not be conducted or supported by the Departments and Agencies adopting the Common Rule (56 FR 12800, June 18, 1991) unless the activities are exempt from or approved in accordance with the common rule. See section 101(b) the common rule for exemptions. Institutions submitting applications or proposals for support must submit certification or appropriate Institutional Review Board (IRB) review and approval to the Department or Agency in accordance with the common rule.

Institutions with an assurance of compliance that covers the research to be conducted on file with the Department, Agency, or the Department of Health and Human Services (HHS) should submit certification of IRB review and approval with each application or proposal unless otherwise advised by the Department or Agency. Institutions which do not have such an assurance must submit an assurance and certification of IRB review and approval within 30 days of a written request from the Department or Agency.

1. Request Type <input checked="" type="checkbox"/> ORIGINAL <input type="checkbox"/> FOLLOWUP <input type="checkbox"/> EXEMPTION	2. Type of Mechanism <input type="checkbox"/> GRANT <input checked="" type="checkbox"/> CONTRACT <input type="checkbox"/> FELLOWSHIP <input type="checkbox"/> COOPERATIVE AGREEMENT <input type="checkbox"/> OTHER: _____	3. Name of Federal Department or Agency and, if known, Application or Proposal Identification No. Department of Defense (DAMD 17-96-C-6091)
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4. Title of Application or Activity CD-ROM Technology to Increase Appropriate Self-Care and Preventive Behaviors Among Army and Navy Women: Needs Assessment Survey for

5. Name of Principal Investigator, Program Director, Fellow, or Other Robert S. Gold, Dr.P.H., Ph.D.

6. Assurance Status of this Project (Respond to one of the following) Military Chiefs of Service

- ☐ This Assurance, on file with Department of Health and Human Services, covers this activity.
Assurance identification no. _____ IRB identification no. _____
- ☒ This Assurance, on file with (agency/dept) Human Use Review and Regulatory Affairs Division/Dept. of the Army covers this activity.
Assurance identification no. S-20027 IRB identification no. _____ (if applicable)

☐ No assurance has been filed for this project. This institution declares that it will provide an Assurance and Certification of IRB review and approval upon request.

☒ Exemption Status: Human subjects are involved, but this activity qualifies for exemption under Section 101(b), paragraph (b)(1) & (b)(2)

7. Certification of IRB Review (Respond to one of the following IF you have an Assurance on file)

☒ This activity has been reviewed and approved by the IRB in accordance with the common rule and any other governing regulations or subparts on (date) 7/11/97 by: ☒ Full IRB Review or ☐ Expedited Review

☐ This activity contains multiple projects, some of which have not been reviewed. The IRB has granted approval condition that all projects covered by the common rule will be reviewed and approved before they are initiated and that appropriate further certification will be submitted.

8. Comments

9. The official signing below certifies that the information provided above is correct and that, as required, future reviews will be performed and certification will be provided.

10. Name and Address of Institution

Macro International Inc.
11785 Beltsville Drive
Calverton, MD 20705

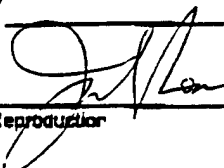
11. Phone No. (with area code)
(301) 572-0208

12. Fax No. (with area code)
(301) 572-0986

13. Name of Official
James G. Ross

14. Title
Vice President and IRB Chair

15. Signature



16. Date

8/6/97

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